

For Pharmacy Providers





### Effective March 1, 2018

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## Introduction to Prime Therapeutics

### Introduction

Prime Therapeutics LLC (Prime) manages pharmacy benefits for health plans, employers and government programs including Medicare and Medicaid. The company processes claims and delivers medicine to Covered Persons, offering clinical services for people with complex medical conditions.

Prime's services include:

- Pharmacy Network management
- Drug Formulary management
- Pharmacy communication
- Drug utilization review (DUR)
- Clinical programs
- Physician education
- Claims processing

Prime manages Pharmacy Networks to provide Prescription Drug Services for our Benefit Sponsors through our online claims processing system. This system gives Participating Pharmacies real-time access to:

- Covered Person eligibility
- Drug coverage information
- Drugs requiring prior authorization
- DUR information

Prime is committed to doing business with integrity in accordance with all applicable federal, state and local laws. Prime has adopted a compliance program and code of conduct. This includes policies and procedures to avoid potential conflicts of interest and Fraud, Waste or Abuse (FWA). Click here to access **Prime's code of conduct**.

Prime requires all Participating Pharmacies to adopt appropriate compliance programs, including:

- Codes of conduct
- FWA programs
- Conflict of interest policies and procedures

### Provider Manual

The purpose of this Provider Manual ("Manual") is to explain Prime's administrative and compliance policies and procedures. The Manual is incorporated into the Prime Therapeutics Pharmacy Participation Agreement ("Agreement"). Prime will update this Manual as necessary at its sole discretion. This version of the Manual supersedes all previous versions of the Manual. Prime posts the most current version of the Manual at **PrimeTherapeutics.com**.

Prime posts relevant instructions, notices, information and supplements or changes to this Manual on the **Prime Website**. Visit **Prime's Website** for up-to-date information and processing instructions.

All capitalized terms that are otherwise not defined in this Manual refer to those defined in the Agreement.

Important: This Manual applies to all lines of business, including, but not limited to Medicare, Medicaid and commercial business.

## Section 1: Prime Contact Information

### Prime Mailing Address

If you would like additional information, contact Prime at:

Prime Therapeutics P.O. Box 64812 St. Paul, MN 55164-9403

### Prime's Contact Center

### 800.821.4795

Prime's Contact Center has dedicated staff to assist you. They can help you with contract requests, processing questions, and any comments and concerns you may have. Prime's representatives are available 24 hours a day, 365 days a year.

### Prime's Website

Visit **Prime's Website** (www.PrimeTherapeutics.com) for the following information:

- Payer sheet
- Medicare Prescription Drug Coverage and Your Rights
- Formularies Commercial
- Formularies Medicare Part D
- Prime Perspective newsletters
- Compliance/Fraud, waste and abuse
- Plan announcements
- Network request form
- Common billing errors
- Minimum Performance and Service Criteria for Medicare Part D Programs
- Minimum Performance Criteria for LTC
- Medicare Part B vs. Part D coverage issues
- Pharmacy Audit Appeal form
- Prime Audit/Fax series
- Long-Term Care and Home Infusion General Dispensing Requirements
- Home Infusion (HI) validation
- Long-term care (LTC) validation
- Medicaid programs
- Vaccine program
- Check Inquiry form
- Maximum Allowable Cost (MAC)

## Section 2: Compliance

### Report Compliance, Privacy, or Fraud, Waste and Abuse Concerns

#### Compliance

Report suspected compliance concerns:

- Phone: 612.777.5523
- Email: compliance@PrimeTherapeutics.com

#### Privacy

Report privacy concerns or potential protected health information (PHI) disclosures:

- Privacy Hotline: 888.849.7840
- Email: privacy@PrimeTherapeutics.com

#### Fraud, Waste and Abuse

If you suspect Fraud, Waste or Abuse (FWA) by a covered person, prescribing provider, participating pharmacy or anyone else, notify Prime:

- Phone: 800.731.3269
- Email: reportfraud@PrimeTherapeutics.com

If you suspect FWA involving the Federal Employees Plan by a covered person, prescribing provider, participating pharmacy or anyone else, notify Prime:

- Phone: 844.765.9990
- Email: FEPreportfraud@PrimeTherapeutics.com

#### **Anonymous Reporting:**

Report a compliance concern or suspected Fraud, Waste or Abuse anonymously by contacting Prime's 24-hour anonymous compliance hotline:

- By phone: 800.474.8651
- By email: reports@lighthouse-services.com
- By third party vendor's website: www.lighthouseservices.com/prime

Please contact Prime's compliance department with any concerns, including:

- Violation of a state, federal, local law, regulation or any governmental guidance
- Conflict of interest
- Acceptance and/or offers of gifts or entertainment
- Fraud, Waste and Abuse
- Improper disclosure of Prime's confidential or proprietary information
- Retaliation for reporting a compliance issue
- Falsification of reports, records or files
- Theft

Participating Pharmacies must develop policies and procedures in compliance with all applicable rules and regulations, including but not limited to Medicare Programs. Participating Pharmacies should have someone who is responsible for establishing a plan to meet Medicare Program requirements and appropriate documentation of that plan. Participating Pharmacies should communicate the plan and any means of enforcing the plan to all employees.

Refer to the Centers for Medicare & Medicaid Services (CMS) website, **CMS.gov**, for a complete list of compliance program requirements.

## Section 2: Compliance (Continued)

### Fraud, Waste and Abuse (FWA)

### **Annual Attestation Requirement**

The annual FWA attestation form is now part of your pharmacy NCPDP profile. Please complete the form via the NCPDP website. For your convenience, training and instructions for completing the NCPDP form are on **Prime's Website**. Failure to attest to the annual general compliance and FWA training may result in termination from Prime's Networks.

### Medicare Part D FWA and General Compliance Participating Pharmacy Training and Certification

CMS requires any staff providing Medicare Part D services to receive qualified Fraud, Waste and Abuse (FWA) and General Compliance training upon hire and annually thereafter. Every year, on behalf of the Part D Plan Sponsors it serves, Prime is required to track completion of this training by all Participating Pharmacies in its network. Participating Pharmacies will be able to submit a single attestation to NCPDP (as part of your pharmacy profile), which will be submitted to Prime. The FWA and General Compliance training needs to be CMS certified to be compliant with the training requirement.

### **Reporting of Suspicious Activity**

Participating Pharmacies and Prime have an obligation to help protect and maintain the integrity of the health care system by promptly reporting suspicious activity.

Participating Pharmacies are expected to exercise due diligence to ensure prescriptions are valid. For example, if the Participating Pharmacy receives a prescription order that appears potentially altered or forged, contact the Prescriber to:

- Validate the prescription
- Document the prescription order with date and time
- Include the representative name from the Prescriber's office

At all times, remain mindful of FWA and report suspicious activity as soon as possible.

Please contact Prime's FWA Department as set forth in the Compliance section of this Manual with any concerns. Examples of potential FWA include but are not limited to:

- Misrepresentation of status A Covered Person or other individual misrepresents personal information, such as identity, eligibility or medical condition in order to illegally receive a drug benefit; or an individual who no longer has prescription drug coverage attempts to use his/her identity card to obtain prescriptions.
- Identity theft An individual uses another person's Medicare or health insurance card to obtain prescriptions.
- **Illegal resale of drugs** A Covered Person falsely reports loss or theft of drugs or fakes illness to obtain drugs for illegal resale.
- **Prescriber shopping**—A Covered Person consults a number of Prescribers to inappropriately obtain multiple prescriptions.
- Script mills A Prescriber writes prescriptions for drugs that are not medically necessary, often in mass quantities, and often for Covered Persons who are not the Prescriber's patients. These prescriptions are sometimes written for drugs found on a schedule of controlled substances for illegal sale. These prescriptions may also result in improper payments to the Prescriber.
- Theft of Prescriber's Drug Enforcement Administration (DEA) number or prescription pad — These are stolen from Prescribers and used to write prescriptions, often for controlled substances or medications which typically are either abused or sold on the black market.
- Inappropriate billing practices Inappropriate billing practices occur when pharmacies engage in billing practices which include, but are not limited to:
  - Incorrect billing for secondary payers to receive increased reimbursement
  - > Billing for non-existent prescriptions
  - Billing multiple payers for the same prescriptions, except as required for coordination of benefits transactions

## Section 2: Compliance (Continued)

- Billing for brand-name drugs when generic drugs are dispensed
- > Billing for non-covered prescriptions as covered items
- Billing for prescriptions that are never picked up (i.e., not reversing claims that are processed when prescriptions are filled but never picked up)
- Billing based on "gang visits" (for example, a pharmacist visits a long-term care facility and bills for numerous pharmaceutical prescriptions without providing prescriptions to Covered Persons)
- > Inappropriate use of product selection codes (PSC)
- > Billing an NDC not used to dispense the prescription
- > Billing an NDC or drug that was never ordered
- Billing an incorrect dosage form (i.e., billing for tablet when powder is used to dispense the prescription)
- > Drug diversion
- Phishing to identify a drug that is covered (i.e., a Participating Pharmacy submits a claim for one drug, received a reject or reverses the claim and resubmits for a new drug within a short period of time)
- Prescription splitting to bypass Point of Sale (POS) messaging requiring a prior authorization
- Billing a greater vial size than what is necessary to supply the ordered dose
- **Prescription drug shorting** A pharmacy provides less than the prescribed quantity and intentionally does not inform the Covered Person or make arrangements to provide the balance, but bills for the fully prescribed amount.
- **Bait and switch pricing** A pharmacy leads a Covered Person to believe that a drug will cost one price, but at POS, the Covered Person is charged a higher amount.
- Prescription forging or altering Existing prescriptions are altered by a Covered Person without the Prescriber's permission to increase the quantity or number of refills.

- Dispensing expired or adulterated prescription drugs — A pharmacy dispenses drugs that are expired or have not been stored or handled according to the manufacturer or FDA requirements.
- **Prescription refill errors** A pharmacy provides a higher number of refills than what was prescribed.
- Illegal remuneration schemes (kickbacks) A pharmacy is offered, solicits, or receives unlawful payment which results in an incentive or reward for switching Covered Persons to different drugs, influencing Prescribers to prescribe different drugs, or steering Covered Persons to plans.
- **TrOOP manipulation** Manipulation of true out-ofpocket (TrOOP) costs by the pharmacy to either push a Covered Person through the coverage gap so the Covered Person can reach catastrophic coverage before being eligible, or to keep a Covered Person in the coverage gap so that catastrophic coverage is never realized.
- Failure to offer negotiated prices A Pharmacy's failure to offer a Covered Person the negotiated price of a drug available to the Covered Person through the Benefit Plan.
- Inappropriate application of therapeutic interchange protocols A Participating Pharmacy dispensing a different covered medication than prescribed without obtaining the Prescriber's consent, when required.

## Section 3: Claims Processing

### General Information

### **Online Claims Submission**

The Participating Pharmacy is required to electronically submit all claims to Prime for all Prescription Drug Services provided to a Covered Person. This includes situations where no Pharmacy Payment from Prime is due.

The pharmacy must provide a Covered Person adequate information as to where the prescription service can be electronically submitted in situations where pharmacist judgment or applicable law permits the denial of prescription drug service.

#### **Online Availability**

The online system is generally available for claims processing 24 hours a day, 365 days a year.

#### **Claim Formats**

- POS claims must be submitted in the current NCPDP format or current industry version.
- Batch claims must be submitted in the NCPDP Batch format or current industry version.
- The Universal Claim Form (UCF) must be submitted for paper claim submissions. UCFs are available on the NCPDP website at NCPDPOnline.org.

For a complete list of required and/or situational processing requirements, refer to the Payer sheets located on **Prime's Website**.

The Participating Pharmacy must review all Point of Sale (POS) messaging for processing information and Payer sheets located on **Prime's Website** for software set up.

In order for Prime to assist Participating Pharmacies with claims adjudication, please email your unique processing codes, condor codes, and/or input codes: PharmacyOps@PrimeTherapeutics.com.

#### **Medicare Reference Materials**

These documents are available on Prime's Website:

- Medicare Prescription Drug Coverage and Your Rights Standardized Pharmacy Notice Instruction
- Medicare Prescription Drug Coverage and Your Rights
- Medicare Part B vs. D Coverage Issues
- Minimum Performance and Service Criteria for Medicare Part D
- Minimum Performance and Service Criteria for LTC
- High Risk Medications for the Elderly

### Eligibility

#### **Covered Person Identification Card**

The Participating Pharmacy shall require a Covered Person to present a Covered Person Identification Card prior to providing a Prescription Drug Service.

The Covered Person Identification Card does not ensure a Covered Person's eligibility. If a Covered Person does not have a Covered Person Identification Card and the Participating Pharmacy is unsure of eligibility, the Participating Pharmacy must use reasonable steps to confirm the identity of the Covered Person through validation of a government issued identification card or contact Prime's Contact Center at **800.821.4795** to obtain accurate Covered Person information prior to dispensing a product or processing a claim.

### **Covered Person Eligibility**

A Covered Person's eligibility can be verified through the POS system during claim adjudication or by contacting Prime's Contact Center. Unless expressly allowed in this Manual, a Covered Person whose eligibility has been verified should never:

- Be denied a Prescription Drug Service (subject to a pharmacist's professional judgment or allowed by applicable law). If drug service is denied based on professional judgment or applicable law, the pharmacy or pharmacist shall provide the Covered Person adequate information as to where the prescription service can be provided.
- Be asked to pay more than is due under the terms of the Agreement.
- Be asked to pay cash and submit a paper claim, unless otherwise allowed by applicable law.

If a Covered Person's eligibility is obtained using an eligibility lookup system, this information must be confirmed with the Covered Person prior to dispensing the product.

In the event a claim is processed using incorrect eligibility, upon notice, Prime may adjust the claim to reflect correct eligibility and corresponding Benefit Plan coverage. If this occurs, Pharmacy shall not bill, charge, collect a deposit from, seek compensation, remuneration or reimbursement from, or have any recourse against any Covered Person, or persons acting on behalf of the Covered Person.

In accordance with 45 CFR § 155.430, Prime may direct the Participating Pharmacy to reverse claims for Prescription Drug Services and any other related actions. If the Participating Pharmacy is unwilling or unable to reverse requested claims, Prime will reverse claims on behalf of the Participating Pharmacy by providing written notice to the Participating Pharmacy.

#### **Schedule II Prescription Dispensing Considerations**

Schedule II drugs may not be dispensed without a Prescriber's written prescription, except in emergency situations, or when dispensed directly by a Prescriber.

A prescription for a Schedule II controlled substance may not be refilled. A separate prescription is required if a Prescriber wishes to authorize continuation of a patient's use of a Schedule II prescription drug beyond the amount specified on the first prescription.

A prescription for a Schedule II controlled substance may be partially filled to the extent permitted by applicable law.

### **Claims Process for Multiples**

When processing claims for multiples with the same birth date and same medication, use the following procedure:

- Process the first claim as usual.
- Attempt to process the second claim as usual.
- If the second claim rejects, contact Prime's Contact Center at **800.821.4795** to verify the multiple-birth eligibility flag has been set.

#### Medicare E1 Eligibility Query

The E1 Eligibility Query is a real-time transaction submitted by the Pharmacy to RelayHealth, the Transaction Facilitator. It helps determine a Covered Person's Medicare Part D coverage and payer order if the Covered Person has insurance through more than one provider. Participating Pharmacies generally submit E1 Queries when Covered Persons do not have their Medicare Part D Identification Card.

Additional information on E1 Transactions can be found at **RelayHealth**.

Pursuant to anti-kickback statute Section 1128B(b) of the Social Security Act, participating Pharmacies should not submit an E1 for pharmaceutical manufacturer copay assistance coupon programs as they are not considered Prescription Drug Services.

### Medicare and Medicaid Dual Eligible Covered Persons

In accordance with Section 42 CFR 422.504(g)(1)(iii), if a Participating Pharmacy provides Prescription Drug Services to a Covered Person who is eligible for both Medicare and Medicaid, the Covered Person will not be held liable for payment and the Participating Pharmacy must (a) accept the Medicare plan payment as payment in full, or (b) invoice the appropriate State source.

### **Best Available Evidence (BAE)**

Covered Persons who are eligible for Low Income Subsidy (LIS) under the Medicare Part D prescription drug program are enrolled in the claim system with the appropriate LIS copay level. If the claims system does not show the correct LIS status for the Covered Person, the Participating Pharmacy is required by Medicare to accept BAE when presented at the POS.

Medicare also requires Participating Pharmacies to assist Covered Persons who believe they are eligible for LIS, but do not have BAE documentation.

For Covered Persons with supporting BAE documentation:

- The Participating Pharmacy must call Prime's Contact Center to request an immediate LIS status update in the claims system.
- The Participating Pharmacy may submit the claim once the claim system is updated with LIS status.
- The Participating Pharmacy must fax a copy of the Covered Person's supporting BAE documentation to Prime's Contact Center at **800.445.7085.**
- Prime will forward the supporting BAE documentation to the Medicare Part D Sponsor, who will then work with CMS to update the Covered Person's LIS status in the CMS system.

For Covered Persons without supporting BAE documentation:

• The Participating Pharmacy should determine if the Covered Person has less than three days of medication remaining (an "immediate need").

- The Participating Pharmacy should contact Prime's Contact Center to begin the process of updating the Covered Person's LIS status; the request must indicate an immediate or non-immediate need.
- Prime will contact the Medicare Part D Sponsor, who will complete the BAE Assistance Worksheet and submit to CMS to validate and/or update the Covered Person's LIS status in the CMS system.
- CMS will update the Covered Person's LIS status within one business day for an immediate need.

#### Hospice Best Available Evidence (BAE)

Covered Persons who are in hospice will have medications for their terminal illness (and related conditions) paid for by their hospice providers. Some medications submitted under Medicare Part D will reject at POS for Covered Persons in hospice care. If the claims system does not show the correct hospice status for the Covered Person, the Participating Pharmacy is required by CMS to accept BAE when presented at the POS.

If the Covered Person has never previously been in hospice:

• The Participating Pharmacy must contact Prime's Contact Center and request a hospice prior authorization (PA). The PA form will then be faxed to the Covered Person, the Covered Person's physician, or to the Participating Pharmacy to give to the Covered Person.

If the Covered Person was in hospice, but has since been released:

- The Participating Pharmacy must fax the Covered Person's letter of revocation to Prime's Clinical Review at **800.693.6703**, indicating one of the following:
  - > The date the revocation is to be effective
  - > The hospice-provided Notice of Medicare Coverage
  - > Notice of Medicare Non-Coverage (NOMNC); or
  - The hospice-provided discharge indicating the Covered Person has left hospice.

### Submitting the Claim

### Bank Identification Number (BIN) and Processor Control Number (PCN)

A BIN and PCN are required when adjudicating claims through the POS system. A list of the BINs and PCNs used to adjudicate claims through Prime's POS system can be found in the Payer sheets on **Prime's Website.** 

### National Provider Identifier (NPI)

- **Pharmacy NPI** A Participating Pharmacy must have a Pharmacy NPI, and all online claims must be submitted with the Pharmacy NPI. Online claims submitted with the Pharmacy NCPDP number will reject.
- Prescriber Identifiers Prime will only accept a valid, active, individual (Type 01) NPI. The Participating Pharmacy must submit the correct Prescriber Identifier at POS. Claims submitted without a valid Prescriber NPI number will reject at POS. Reject code "619" will be displayed with message "PrescrTyp1NPI Required." The Pharmacy may, through the use of a Submission Clarification Code (SCC), attest that the Prescriber NPI number supplied at POS is or will soon be a valid NPI. The Participating Pharmacy must submit the Prescriber's NPI for all Medicare Part D claims. Claims will be monitored on a daily basis to ensure they are submitted with the correct Prescriber Identifier.

Prime will contact the Participating Pharmacy to request that it correct any claims submitted with an invalid Prescriber Identifier and to update its system for future claims. Failure to resubmit the claim(s) or update the Participating Pharmacy's system for future claims with the correct identifier may result in termination from Prime's Networks.

#### **Medicare Enrollment**

As of the CMS compliance date, CMS requires Prime to reject a Participating Pharmacy claim for a Medicare Part D drug if the Prescriber or eligible Pharmacy Professional:

- Is not enrolled in the Medicare program
- Does not have approved status

- Does not have a valid opt-out affidavit on file with a Medicare Part A and Part B Medicare Administrative Contractor (A/B MAC).
- Is not one of the following Other Authorized Prescribers:
  - Prescribers other than physicians and eligible professionals who are permitted by state or other applicable law to prescribe medications.

To prevent unintended interruptions in coverage and potential harm to beneficiaries, Pharmacy claims and beneficiary requests for reimbursement for Medicare Part D prescriptions written by Other Authorized Prescribers shall not be rejected at the POS if all other requirements are met.

Reject Codes include:

- 773 'Prescriber Is Not Listed On Medicare Enrollment File'
- 774 'Prescriber Medicare Enrollment Period Is Outside Of Claim Date Of Service'
- 829 'Pharmacy Must Notify beneficiary: Claim not covered due to failure to meet Medicare Part D active, valid prescriber NPI requirements'

#### Documentation

Approved and/or confirmed verbal changes and clarifications to the Prescriber's prescription order must be documented on the original hard copy or electronically noted in the Participating Pharmacy's online system prior to dispensing. The Participating Pharmacy should not request changes to a prescription for the sole purpose of avoiding POS messaging. For example, if a Participating Pharmacy receives a POS message indicating a PA is required or that it must call Prime's Contact Center, the Participating Pharmacy is expected to follow the POS messaging and Prime's Contact Center instructions. Electronic documentation must be noted prior to dispensing and must have a system assigned user, date and time stamp in order to take the place of hard copy documentation. When additional refills are ordered, a new prescription number must also be assigned and appropriately documented on a hard copy.

### Days' Supply for Non-Medicare Part D Claims

The Participating Pharmacy must submit the number of consecutive days' supply the prescription product will last that falls within the Covered Person's benefit. Future refills may be rejected if the days' supply is inaccurately submitted.

For prescription products that cannot be broken (such as inhalers), where the smallest unit exceeds the benefit days' supply, the Participating Pharmacy must submit the maximum days' supply allowed under the benefit.

Example: Covered Person's benefit allows up to a 30-day supply. One inhaler will last 40 days. The Participating Pharmacy must bill the inhaler as a 30-day supply.

In situations where one unit does not maximize the benefit's days' supply (such as inhalers) the Participating Pharmacy must submit only the quantity that falls within the benefit.

Example: Covered Person's benefit allows up to a 30-day supply. One inhaler will last 28 days. The Covered Person receives one inhaler as a 28-day supply. This varies by Benefit Plan.

#### Days' Supply for Medicare Part D Claims

The Participating Pharmacy must submit the number of consecutive days' supply the prescription product will last that falls within the Covered Person's benefit. Future refills may be rejected if the days' supply is inaccurately submitted. There are some prescription products that cannot be broken in which the calculated days' supply may exceed common values (i.e., greater than 30 days or greater than 90 days). In these instances, the pharmacy should submit the accurately calculated days' supply.

# *Example: Prolia for a 180-day administration should be submitted with a 180-day supply.*

A small subset of prescription products cannot be broken. For this subset, the smallest unit exceeds the maximum benefit days' supply and there is subjectivity in calculating a day's supply (such as topical products). For these, the Participating Pharmacy must submit the maximum days' supply allowed under the benefit. Example: Covered Person's benefit allows up to a 30-day supply. One unbreakable unit may last 40 days, depending upon the amount used, but a course of therapy should be limited to 28 days (for example, clobetasol shampoo). The Participating Pharmacy must bill the bottle as a 30-day supply.

In situations where one unit does not exceed the maximum benefit days' supply (such as inhalers) the Participating Pharmacy must submit only the quantity that falls within the benefit.

*Example: The benefit allows up to a 30-day supply. One inhaler lasts 28 days. The Covered Person receives one inhaler as a 28-day supply. This will vary by Benefit Plan.* 

#### **Accurate Quantity**

The quantity dispensed must be equal to or less than the quantity written and accurately reflect the exact quantity dispensed to the Covered Person. Submit the exact quantity, including decimal points, on claims and do not round up or down.

#### Dispensed Package Size/National Drug Code (NDC)

When the Participating Pharmacy submits a claim for a Prescription Drug Service provided, the Participating Pharmacy must submit the NDC number for the original package size from which the Prescription Drug Service was dispensed. The quantity of the prescription drug dispensed shall comply with the dispensing limitations obtained through the online POS system.

Prescriptions may not be separated and dispensed by doses. If separate packaging is required, the Participating Pharmacy must use a duplicate label. For example, a dose required in school or adult care center should not be dispensed as a separate prescription.

#### **Timely Filing**

The Participating Pharmacy agrees to submit all claims online within 90 days of the date of Prescription Drug Service, unless otherwise required by law.

### **Medicare E-prescribing**

If the Participating Pharmacy participates in the Medicare electronic prescribing ("e-prescribing") program by receiving or transmitting electronic prescriptions or prescription-related information, the Participating Pharmacy agrees to comply with applicable e-prescribing standards as established by CMS.

#### **Prescription Origin Code**

The Participating Pharmacy must submit all claims with the corresponding prescription origin code:

- > Written
- Telephone
- > Electronic
- > Facsimile
- > Pharmacy

Regardless of whether a Participating Pharmacy is participating in e-prescribing, all claims submissions must indicate the prescription origin code in order to facilitate CMS reporting and tracking of e-prescribe participation. The documentation retained by the Participating Pharmacy must support the prescription origin code submitted on the claim.

# Requirements for Participating Pharmacies Contracted with 340B Covered Entities

The 340B Drug Pricing Program requires drug manufacturers to provide outpatient drugs to eligible health care entities at significantly reduced prices.

42 USC 256b(a)(5)(A)(i) prohibits duplicate discounts; that is, manufacturers are prohibited from providing drugs at a discounted 340B price and a Medicaid drug rebate for the same drug. The Participating Pharmacy must have mechanisms in place to prevent duplicate discounts. Aside from the Participating Pharmacy's obligation to follow the claims processing requirements for 340B claims, Prime may, at its discretion, reverse ineligible claims or incorrect claim submissions for a 340B claim. Prime will recoup any money incorrectly paid through the Pharmacy audit process. The Participating Pharmacy will be notified of the error. To view the specific claim processing requirements for Prime's Medicaid Programs, please go to **Prime's Website**.

#### **Compound Prescription Billing Guidelines**

Participating Pharmacies must submit Compound Prescription claims through the POS system using the following directions:

- Submit Compound Prescription with a code of "2" in the Compound Code field.
- Submit a zero (0) in the Product/Service ID field in the claim segment and submit the information for each ingredient in the compound segment.
- Enter the product ID qualifier, NDC used to prepare the Compound Prescription, quantity, cost and cost basis for each ingredient in the Compound Prescription.
- Submit the final product quantity (the quantity of the finished Compound Prescription product):
  - For a liquid, submit the number of mL of the finished compound product
  - For capsules, submit the total number of capsules being dispensed
  - For creams or ointments, submit the total number of grams being dispensed
- Submit the total ingredient cost. (For total ingredient cost, multiply the quantity used for the individual ingredient and the AWP for the individual ingredient according to the Pricing Source at the time of dispensing for each eligible ingredient used. Then, calculate the total sum of the individual ingredient costs.)
  - Plan-excluded drugs and invalid NDCs are not eligible for reimbursement
  - Eligible ingredient costs do not include costs for labor, equipment, professional fees or flavoring
- Maintain a Compound Prescription log with documentation for each Compound Prescription dispensed. The log must document quantities and NDCs of the ingredients used to prepare the Compound Prescription. NDCs submitted for the Compound Prescription must be the exact formulation of what is dispensed.

- Prime will accept a multiple ingredient Compound Prescription submission using NCPDP's compound segment for up to 25 ingredients.
- Dynamic prior authorizations (PAs) for processing Compound Prescriptions that contain situational Medicare Part B versus Medicare Part D drugs will not apply, even if the compound meets the criteria for inclusion as a Medicare Part D covered drug. A one-time PA will be issued if the Compound Prescription claim meets the criteria for coverage under Medicare Part D.
- If a Compound Prescription claim rejects, the Participating Pharmacy must follow POS messaging to determine if the ingredients submitted require a PA. If a PA is required, the Participating Pharmacy must follow the POS messaging to obtain a PA. If a PA is not required and one or more ingredients is not covered by the Covered Person's Benefit Plan, the Participating Pharmacy may submit a clarification code of "08" to receive payment for all covered ingredients. Not all benefit plans support the use of clarification "08."
- Each benefit set-up determines claim coverage and may vary by Covered Person. As the Compound Prescription claim is processed, the Participating Pharmacy receives system messaging on the status of the submission. Participating Pharmacies are required to follow all system messaging.
- Compound Prescriptions containing a Medicare Part B ingredient must be processed under Medicare Part B.

Participating Pharmacies are expected to observe applicable state and federal laws, relevant U.S. Pharmacopoeia (USP) Chapter Guidelines, professional standards and FDA communications when preparing and dispensing Compound Prescriptions. Evidence of unprofessional or unsafe compounding found during the Participating Pharmacy's audit process or otherwise may be reported to the applicable State Board of Pharmacy or the FDA, and may result in termination of the Pharmacy Participation Agreement.

Prime administers pharmacy benefits on behalf of many different Benefit Sponsors. Each individual Benefit Sponsor determines Benefit Plan design, such as the specific drugs/ingredients covered, cost-sharing, days' supply limitations, and other benefit design attributes. The following are examples of Compound Prescription drugs where benefit designs may vary:

- Modified-release compounds (based on Covered Person benefit design).
- Any compound that contains active ingredients not approved by the FDA.
- A compound for which the stability is unknown at the time of dispensing or cannot be determined by reference of an USP-approved reference material.
- For Medicare business:
  - > Compound components
  - > Methods of administration
- Other criteria that do not satisfy the definition of a Medicare drug
- Experimental/investigational items, products or services.
- Any finished product intended to address medical diagnosis (such as sugar-free products) where the Covered Person's medical diagnosis does not support the need for the finished product.
- Any compound that differs from the equivalent commercial form only by the addition of cosmetic agents or agents intended to produce a cosmetic effect.

The following drugs cannot be submitted to Prime as a Compound Prescription:

- Reconstituted non-sterile products, to which only water, alcohol or sodium chloride solution are added to the active ingredient (for example, children's antibiotic suspensions, antibiotic IVs with only one legend drug).
- Any prescription that is subdivided into unit dose(s).
- Injectable drugs that are drawn into syringes for administration.
- Any finished product that does not include a Federal Legend Drug as an ingredient.
- Any compound that has an equivalent commercial form, except in situations where a Compound Prescription is preferred according to the Benefit Plan. This exception may vary by state.

Prime also considers the following to be additional unacceptable billing practices for Compound Prescription claims:

- Billing for a different NDC than what was used in the Compound Prescription.
- Billing for the full package size when only a partial amount was dispensed to the patient.
- Billing for a different dosage form than what was used in the Compound Prescription.
- Billing for a quantity other than what was actually used to prepare the Compound Prescription.
- Any Compound Prescription to which active ingredients are added that were not part of the prescription order.
- Not following POS messaging, including but not limited to messaging for rejected claims.
- Obtaining changes to Compound Prescription orders to avoid POS messaging.
- Phishing for a drug that pays (i.e. Participating Pharmacy submits a claim for one drug, received a reject or reverses the claim and resubmits for a new drug within a short period of time.)
- Billing each compound ingredient as a separate Prescription Drug Service claim.
- Billing claims in a manner that bypasses system messaging requiring further review.
   Example: billing claims multiple times in a month to avoid obtaining a PA or reaching plan dollar thresholds.
- Billing claims for a new order prior to verifying the Prescriber/Covered Persons' relationship.
- Billing Compound Prescription claims for a Covered Person:
  - Where there is not literature that supports the clinical use
  - > Where the Participating Pharmacy is not registered as a 503B entity with the FDA
  - From a central fill pharmacy that is not contracted with Prime
  - In a manner that violates any federal, state or local law regarding compounding, marketing and/or dispensing compound medications

- That resulted in the Participating Pharmacy giving or receiving payment to or from any Prescriber for referrals
- Balance billing for any products that are not eligible for payment determined by the plan sponsor and/or CMS

If you have questions regarding compound drugs, please contact Prime's Contact Center at **800.821.4795.** 

### **Insulin and Diabetic Supply Benefits**

- A valid prescription must be on file for insulin dispensed to a Covered Person.
- Insulin should be dispensed within the days' supply limits set by the Covered Person's Benefit Sponsor.
- Specific dosing directions must be documented at the time of dispensing. If a sliding scale is used, the Participating Pharmacy must obtain and document maximum and minimum quantities at the time of dispensing. Directions limited to "Use as Directed" are not accepted.

#### **Insulin Supplies**

- Unless otherwise indicated at POS, insulin syringes and needles are a covered benefit.
- A valid prescription is required for insulin supplies to be dispensed to a Covered Person.
- Some Benefit Sponsors will waive the Copay for insulin supplies dispensed at the same time as insulin. In this situation, the insulin must be processed first.
- Diabetic supplies submitted to insurance are considered prescriptions, and must follow all terms and conditions outlined in this Manual.

### Long-Term Care (LTC) and Home Infusion (HI) Processing Requirements

Prime requires LTC and HI Participating Pharmacies to submit NCPDP D.0 fields as outlined on the Payer Sheets. Processing guidelines for submitting LTC and HI claims are located on **Prime's Website**.

#### Hemophilia Billing Guidelines

Pharmacies are expected to maintain accurate records of a hemophilia patients' available on-hand supply in order to support appropriate future dispensing. Patient bleed records must be collected and maintained by the Pharmacy. Pharmacies are expected to ensure that patients have an emergency bleed supply on-hand for major and minor bleeds. If a bleed occurs, the pharmacy may replenish the on-hand bleed supply.

Single use vials should be dispensed in a manner that most closely aligns with the prescribed dose. If a Participating Pharmacy dispenses clotting factor with an assay of greater than 5% variance of the prescribed dose, the pharmacy must document the reason the assay was not met at the time of dispensing. Factor products must have expiration dates of no less than one year from the date of dispensing unless there is specific documentation of discussing this with the patient or caregiver. Doses dispensed for as needed use for bleeds should not be dispensed with an expiration of less than one year. Dispensing more units per dose than what is necessary or dispensing short-dated product may result in a financial recovery.

### Medicare Programs Coordination of Benefits (COB)

COB claims for Medicare Programs should be processed in Prime's claims processing system. Participating Pharmacies must submit the primary claim to Prime electronically. After Prime adjudicates the claim, Prime will provide POS messaging that contains the claim transaction information and the Covered Person's supplemental coverage record if Prime is aware of other supplemental coverage. This POS messaging generally accommodates supplemental plans and includes information to process the supplemental claim(s). Supplemental claims must be processed through a switch to capture these transactions for accurate TrOOP calculations. This process is designed to function in real time and to process all levels of payer submissions for a claim at the POS. When the primary payer or payer order information is not known or is in doubt, the pharmacist can send an E1 Eligibility Query to RelayHealth to determine proper payer order. Prime's Supplemental to Medicare Payer sheets are available on **Prime's Website**.

Additional information on Medicare COB can be found at **CMS.gov**.

#### **Time Limits for Coordination of Benefits**

There are time limits for coordinating benefits with State Pharmaceutical Assistance Programs, other entities providing Prescription Drug Service or other payers. The time limits cannot exceed three years from the date the prescription for the Medicare drug was filled. This does not affect time frames for Medicare secondary payer (MSP) prescription drug claims and the ability to recover amounts.

#### Medicare Parts A & B vs. D Claims Adjudication

Medicare Part D excludes any drugs covered under Medicare Part A or Part B, such as drugs that are administered in a pump, covered under hospice benefits or End Stage Renal Disease (ESRD) benefits. Participating Pharmacies are responsible for ensuring that claims eligible for coverage under Medicare Part A or Part B are not adjudicated under Medicare Part D. For example, insulin, when used in a pump, should be billed under Medicare Part B.

In the event that insulin is being used in a pump, the Participating Pharmacy must submit the claim to Medicare Part B. On applicable insulin products, a POS message will be returned on the claim that states "If used in non-disposable pump, submit to Medicare Part B." The Participating Pharmacy must verify insulin is not being used in a pump before submitting the claim to pay under Medicare Part D.

Participating Pharmacies that serve LTC facilities are required to determine potential Medicare Part A eligibility by reviewing Medicare Part A eligibility information with their contracted LTC facilities. Participating Pharmacies should seek payment from the LTC facility for Prescription Drug Services for Covered Persons under a qualifying and covered Medicare Part A stay.

Prime provides POS messaging on certain claims that may be eligible for coverage under Medicare Part A or Part B depending on the Covered Person's circumstance. For example, Participating Pharmacies may receive an NCPDP Reject Code of 569, indicating 'Provide Notice: Medicare Prescription Drug Coverage and Your Rights,' requiring the Participating Pharmacy to distribute the Prescription Drug Coverage and Your Rights form. This written notice informs Covered Persons of their right to request and receive a coverage determination. The Participating Pharmacy must take appropriate steps, as necessary, to ensure Medicare Part A and Part B eligible claim(s) are not adjudicated under Medicare Part D.

A Participating Pharmacy must promptly reverse the Medicare Part D claim(s) after determining that it was eligible for coverage under Medicare Part A or Part B, and refund any Medicare Part D cost-sharing collected from the Covered Person.

Aside from the Participating Pharmacy's obligation to reverse ineligible claims, Prime may, at its discretion, reverse ineligible Medicare Part D claims. Prime conducts outreach to Participating Pharmacies to reverse previously adjudicated claims that have been identified with a retroactive ESRD date of service, or claims where insulin is used in a pump. The Participating Pharmacies must reverse the identified claim(s) and resubmit to the Covered Person's correct Medicare Part A or Part B coverage. If the Participating Pharmacy fails to reverse the claim as directed, Prime will reverse the claim on its behalf.

If a Participating Pharmacy mistakenly bills Medicare Part D for a drug where coverage is available under Medicare Part A or Part B, Prime will recoup any money incorrectly paid through the pharmacy audit process and notify the Participating Pharmacy of the error. Retroactive recoupment for hospice drugs may be coordinated directly with the hospice and/or Covered Person. For more information, refer to the Medicare Part B vs. Part D Coverage Issues document on **Prime's Website**.

For additional processing requirements, refer to the Payer sheets on **Prime's Website**.

### Utilization Management Program

### **Drug Formularies**

Prime manages many Drug Formularies for Benefit Sponsors and administers them through the POS system and can be accessed on **Prime's website**.

#### Medicare Drug Formularies

Medicare formularies for the following year are published on **Prime's Website** beginning in October prior to the year they become effective. Medicare formularies are updated on a monthly basis to reflect additions, deletions, tier changes and utilization management changes. Updated lists are posted monthly on **Prime's Website**.

During the benefit year, Prime will notify affected Covered Persons and Prescribers of certain Drug Formulary changes at least 60 days before the change becomes effective. Changes will also be posted on **Prime's Website**. These changes may include:

- Drugs that are removed from the Drug Formulary.
- Changes to prior authorization (PA), quantity limits and/or step therapy programs to be more restrictive.
- Drugs that have moved to a higher cost-sharing tier.

If the FDA declares a drug to be unsafe, or the drug's manufacturer removes the drug from the market, then Prime will remove the drug from the Drug Formulary and provide notice to Covered Persons who have received the drug.

Covered Persons may be notified of Drug Formulary changes by United States Postal Service, email or when they check their plan's website. Prescriber and Participating Pharmacy Drug Formulary notifications are available on **Prime's Website**. To view the comprehensive list of Medicare formularies, visit **Prime's Website**.

### **Prior Authorization (PA)**

Below are the six (6) types of PAs used by Prime:

- One-time override Used for a dosage change, vacation, lost/stolen, spilled, incorrect days' supply, damaged medication or retail to mail. At the time of the fill, the Participating Pharmacy must document the reason for the override on the hard copy or within an electronic system. Electronic notes are only considered acceptable documentation when the Participating Pharmacy's system automatically dates and time stamps the entry. The Participating Pharmacy may request PA for a dosage change or vacation request by calling Prime's Contact Center at **800.821.4795.**
- Dynamic PA Some Benefit Sponsors use an automatic override process referred to as dynamic PA. A Participating Pharmacy enters a pre-determined PA number for certain conditions, such as a vacation request, adverse weather, or dosage change. At the time of the fill, the Participating Pharmacy must document the reason for the override on the hard copy or within an electronic system. Electronic notes are only considered acceptable documentation when the Participating Pharmacy's system automatically dates and time stamps the entry. A Participating Pharmacy may need to request a PA for a dosage change or vacation override.

#### The following PA's must be completed by the Prescriber:

- Drug Formulary exception Used for Covered Persons sensitive or unresponsive to the Drug Formulary medication requested by the Prescriber. If the Benefit Sponsor has elected to use this PA, Prime will provide the Participating Pharmacy POS messaging for additional instructions on requesting a Drug Formulary exception. In no event shall the Participating Pharmacy complete a PA for a Drug Formulary exception. The Participating Pharmacy shall follow POS messaging and notify the Covered Person and/or Prescriber of the need for a PA. There are three ways to obtain a Request for a Drug Formulary Exception form:
  - The Prescriber can contact the Benefit Sponsor by phone or in writing based on the information provided on the Covered Person's Identification Card

- The Covered Person can call the Covered Person service toll-free number on the back of the Covered Person's Identification Card
- The Covered Person can visit his or her Benefit Sponsor's website
- **Clinical PA** Used for medication that requires clinical review of specific criteria to be met before the medication is covered by the Benefit Sponsor. If the Benefit Sponsor has delegated this function to Prime, then Prime will review the PA request to determine if the Covered Person is eligible for coverage. In these cases, Prime requires clinical documentation from the Prescriber. In no event shall the Participating Pharmacy complete a PA for Clinical PA. The Participating Pharmacy shall follow POS messaging and notify the Covered Person and/or Prescriber of the need for a PA. POS messaging may vary based on the drug or program and may include quantity limit, step therapy or clinical necessity requirements in addition to the PA. Regardless, Covered Persons should always contact the service department at their Benefit Sponsor if they have any questions. Examples of medications included in the clinical PA program are growth hormones or pegylated interferons or compounds. These drugs will reject with the NCPDP reject codes of 75, "Prior Authorization Required" or 76 "Plan Limitations Exceeded." For the most current information on medication that requires PA, visit the Covered Person's Benefit Sponsor's website.
- Appropriate Payor verification This PA is used specifically for certain drugs (such as Cialis and fentanyl) in Medicare Part D that have the highest likelihood of non-Medicare Part D covered uses. Claims for these drugs should reject at POS and require a PA to determine that:
  - > The Covered Person's use of that drug is eligible for coverage under Medicare Part D
  - The Covered Person's use of that drug satisfies any of the Benefit Sponsor's CMS-approved utilization management criteria

NOTE: Medicare Part D Transition — If a Covered Person is within the transition period, the Covered Person will not immediately receive a temporary supply of these drugs as a Covered Person would for other drugs that are covered under Medicare Part D. Following Prime's review of a PA request for one of these drugs, Prime may determine that the Covered Person's use of that drug is covered under Medicare Part D but is not covered under the Benefit Sponsor's CMS-approved utilization management criteria. In these cases, Prime may conduct outreach to the pharmacy where the initial claim rejected and inform that pharmacy that the Covered Person is eligible to receive a temporary supply of these drugs during the remainder of the Covered Person's transition period.

- Hospice PA CMS has determined the following categories of drugs to be generally payable under Medicare Part A when prescribed to Covered Persons that have elected hospice:
  - 1. Laxatives
  - 2. Antiemetics
  - 3. Antianxiety agents
  - 4. Analgesics (nonnarcotic, opioid and antiinflammatory)

Claims will reject with the NCPDP reject codes of A3 "Product May Be Covered Under Hospice — Medicare A," and 75, "Prior Authorization Required." The Participating Pharmacy should generally work with the Hospice Care provider for payment for drugs within the four categories listed above. However, if the Hospice Care provider (or non-hospice Prescriber) determines that a drug within one of these four categories is unrelated to the Covered Person's terminal illness or related condition, the drug would be eligible for coverage under Medicare Part D.

In this case, a Hospice PA is required. The drug may still need to satisfy any other existing utilization management criteria in order to be payable under Medicare Part D. The Covered Person's Prescriber can follow the standard coverage determination process to request a Hospice PA. Additionally, the Hospice Care provider can submit a Hospice PA Form on the Covered Person's behalf to request the Hospice PA. • If the Covered Person's eligibility incorrectly states that they are actively enrolled in Hospice and their claim for a drug in these four categories rejects at the Participating Pharmacy, a Hospice PA may be required in order to override the incorrect eligibility and allow the Covered Person's claim to adjudicate. As mentioned above, the Covered Person's Prescriber can submit a coverage determination or the Hospice Care provider can submit the Hospice Prior Authorization Form in order to request the Hospice PA. The Participating Pharmacy may request a Hospice PA Form by calling Prime's Contact Center at **800.821.4795.** 

# Electronic Submission of PA Requests Supported by CoverMyMeds

If the Participating Pharmacy has received POS Clinical PA messaging, the Participating Pharmacy may initiate an electronic PA request through **CoverMyMeds.com**. In any event, the Participating Pharmacy must notify the Covered Person and/or Prescriber indicating that a PA is required for the Prescription Drug Service. In no event, shall the Participating Pharmacy complete a PA on behalf of a Prescriber. See **CoverMyMeds** for more information.

### Step Therapy/Contingent Therapy Programs

Some Benefit Sponsors require the Covered Person to try one or more preferred medications before a nonpreferred medication is considered for payment. This is referred to as step therapy. Refer to the Benefit Sponsor Drug Formulary to determine if a drug is subject to step therapy. Examples of medications that may be included in step therapy programs include topical non-steroidal medications and xanthine oxidase inhibitors/renin inhibitors and proton pump inhibitors. For the most current information on step therapy, visit the Covered Person's Benefit Sponsor's website. These drugs will reject with the NCPDP reject codes of 75 "PA required" or 608 "Step Therapy Alternate Drug Therapy Required Prior to Use of Submitted Product Service ID" and 76 "Plan Limitations Exceeded." POS messages will vary based on the drug or program and may include quantity limit, step therapy or clinical necessity requirements in addition to PA.

### **Quantity Limit**

Many Benefit Sponsors restrict the quantity that may be dispensed on certain drugs, such as proton pump inhibitors or tobacco cessation medications. These limits follow clinical dosing guidelines and restrict the dispensing of the drug to a maximum quantity. When submitting a claim that exceeds the maximum quantity, the claim will receive NCPDP reject code 76 "Plan Limits Exceeded." A free-form text message accompanies the rejection and indicates the maximum quantity that may be dispensed, assuming the prescription order is for at least that amount. A Participating Pharmacy must electronically accept Prime's POS messaging. This section titled "Quantity Limit" does not apply to Prescription Drug Services where a Participating Pharmacy receives a rejection message at the POS indicating "Prior Authorization Required," "Call Pharmacy Help Desk" and/or "Plan Dollar Limit Exceeded."

If the quantity exceeds the Covered Person's benefit, the Participating Pharmacy must reduce the quantity prescribed and provide refills. If the Covered Person requests a smaller amount, the Participating Pharmacy may reduce the quantity prescribed. The pharmacist should document this on the hard copy at the time of the fill or prior to dispensing on the electronic documentation to reflect the Covered Person's request. Electronic documentation must have a system-assigned user, date and time stamp in order to take the place of hard copy documentation.

### Drug Utilization Review (DUR)

Prime monitors drug utilization to support the Pharmacy Professional in providing quality care to all Covered Persons. Prime will alert Participating Pharmacies through the POS system in situations that include, but are not limited to:

- Drug regimen compliance screening
- Drug drug interaction screening
- Drug inferred health state screening
- Dosing/duration screening
- Drug age caution screening
- Drug sex caution screening

- Duplicate prescription screening
- Duplicate therapy screening
- Additive toxicity screening
- Apparent Drug Misuse screening

The Participating Pharmacy is responsible for reviewing any claim with a DUR alert from the POS system. The Participating Pharmacy is responsible for ensuring that its systems accept DUR messaging. Pharmacists should use professional judgment to follow up with Covered Persons and counsel them regarding the DUR messages.

Prime's concurrent DUR edits during the claim submission and adjudication process are important steps toward complying with CMS regulations; however, they are not the only appropriate measures. Prime requires Participating Pharmacies in Prime's Medicare Programs Network to review, update and/or implement quality assurance systems and procedures at the POS to ensure compliance with CMS regulations. Participating Pharmacies are required to obtain and refer to the Covered Person's allergy information before dispensing. In addition, Participating Pharmacies must ensure that all employees or other agents who dispense medication are aware of and use these DUR procedures, and that they follow currently accepted standards for contemporary pharmacy practice as established by the applicable jurisdiction.

#### Maximum Allowable Cost (MAC)

Prime's MAC program includes drugs that are reimbursed at an upper limit per unit price. All products are reviewed on a regular basis and will be adjusted as-needed based on market conditions. If the availability of a drug becomes limited, the MAC will be temporarily suspended or the drug may be permanently removed from the MAC lists at Prime's sole discretion. The drug may be added back when Prime's market sources confirm adequate supply and distribution. If a Participating Pharmacy would like access to Prime's MAC lists, weekly MAC changes, MAC pricing appeals process, and the sources used to determine MAC pricing, please refer to **Prime's Website** for registration instructions. After Pharmacy Network participation is verified, the Participating Pharmacy will receive a secure user name and password via email to access Prime's MAC lists.

### Post Claim Adjudication

### Return to Stock — Unclaimed Prescriptions

Participating Pharmacies are required to reverse any claim that is not delivered to or received by the Covered Person within 14 days of submission, unless a shorter time period is required by law, per the terms of the Prime's Pharmacy Participation Agreement. Claims not reversed within 14 days that are not received by the Covered Person are subject to audit and may be collected through the retrospective pharmacy audit process.

## Section 4: Benefit Plan

### Benefit Plan

Existing benefits may change without prior notice to the Participating Pharmacy. New Benefit Plans may be added at the request of a Benefit Sponsor. The POS system will provide the Participating Pharmacy with current benefit information.

Brief explanations of common benefit designs are listed in the following sections. Keep in mind that these conditions may or may not apply to a particular Benefit Sponsor.

## Long-Term Care (LTC) Guidelines

For Participating Pharmacies providing Prescription Drug Services to Covered Persons residing in an assisted living facility or other forms of congregate residential setting, the Covered Person must meet the same institutionalized level of care as a Covered Person residing in an LTC facility in order to be eligible for LTC reimbursement. At the time of dispensing, the level of care must be documented on the prescription hard copy or the electronically submitted prescription.

## Services Provided to Family Members

In accordance with Covered Person's Benefit Plan, Prescription Drug Services prescribed by or provided to a family member may not be covered and such Prescription Drug Services may be subject to financial recovery.

## Product Selection Code (PSC)

For purposes of this Manual, Dispense as Written (DAW) and PSC are used interchangeably. A Participating Pharmacy must submit an accurate PSC, in accordance with NCPDP specifications, when processing claims electronically. PSC submissions may change the calculation of the claims adjudication depending upon the Benefit Plan. Misuse of any PSC code may lead to recoupment by pharmacy audit.

### Generic Substitution

PSC 1: Prime encourages Participating Pharmacies to dispense generic drugs whenever possible. However, there are instances where the Prescriber may request that a brand-name product be dispensed instead of the generic equivalent drug. These claims must be submitted with a PSC of 1. If a PSC of 1 is used in processing a claim, the prescription order, at the time of the fill, must contain documentation of the DAW order from the Prescriber. If the prescription is telephoned in, the pharmacist must manually write "DAW" on the prescription so it is documented in writing.

PSC 2: In addition, Covered Persons may request a brand-name product be dispensed instead of the generic equivalent. A Participating Pharmacy must document or have a computer time and date stamp on the prescription that the Covered Person requested the brand-name product and submit the claim using a PSC of 2.

The Covered Person's Copay for PSC 1 or 2 may vary based on the Benefit Plan design. Some Benefit Sponsors may require the Covered Person to pay the difference between the brand-name product and the generic equivalent.

### **Generic Drug Standards**

A Participating Pharmacy must dispense a generic drug whenever permitted and in accordance with applicable laws.

A Participating Pharmacy must stock a variety of generic drugs coinciding with the habits of Prescribers and/or Benefit Sponsor's Drug Formulary as indicated by the claims system response and other correspondence, or the generic Drug Formulary of the state in which the Participating Pharmacy is located.

### **Enhanced Pharmacy Programs**

### **Vaccine Administration**

Participating Pharmacies that dispense and administer Vaccines must follow all applicable laws, regulations and guidelines governing the sale and administration of Vaccines including ensuring proper personnel compliance and licensing. Please refer to **Prime's Website** for up-to-date Vaccine program information.

"Vaccine" means a specially prepared antigen, which upon administration to a person, will result in immunity, or any other definition that is required by applicable law. "Vaccine Administration Fee" means a fee payable to the Participating Pharmacy for administering a Vaccine by the act of injection in accordance with applicable law. A Participating Pharmacy must submit its claim for the Vaccine Administration Fee to Prime electronically, along with the related ingredient cost submission and dispensing fee. In other words, the ingredient cost, dispensing fee and Vaccine Administration Fee must be submitted to Prime as a single claim. Visit **Prime's Website** for processing instructions, including software set up for the vaccine administration program.

### **Medication Therapy Management (MTM)**

Prime is committed to optimizing therapeutic outcomes by improving the use of drugs in order to avoid adverse drug events. Prime does this through both an internal MTM department and external MTM vendors that provide annual Comprehensive Medication Review (CMR) services for MTM-enrolled Covered Persons. Prime also provides quarterly, criteria-based Targeted Medication Review (TMR) services to MTM-enrolled Covered Persons.

Prime enrolls Covered Persons into the MTM program who meet specific criteria. Eligible Covered Persons can complete a CMR by contacting Prime's Contact Center at **866.686.2223.** 

### Medicare Part D Transition Process

CMS requires that Medicare Part D Benefit Sponsors support an appropriate transition process to provide Covered Persons with a temporary supply of prescription drugs in certain circumstances, including, but not limited to:

- Current drug therapies not included in their new Medicare Part D Benefit Sponsor's Drug Formulary.
- Current drug therapies subject to certain limits such as a prior authorization (PA), step therapy (ST) and/or quantity limits (QL).

The transition process gives Covered Persons time to work with their Prescriber to switch to a therapeutically equivalent medication or to get a Drug Formulary exception or PA.

### Prescription Drugs Not on Medicare Part D Benefit Sponsor's Drug Formulary or Subject to Certain Limits

When a Covered Person in their transition period (for example, within ninety (90) days of their eligibility) presents a prescription for a Part D drug that is not on the Medicare Part D Benefit Sponsor's Drug Formulary or is subject to certain limits such as PA, ST, and/or QL the paid transition claim will return the applicable NCPDP approved message code "004" to the Participating Pharmacy explaining the drug paid due to the standard transition benefit.

### **Supply Limits**

If the claim is submitted for a days' supply greater than what is allowed during the transition period, or if the Covered Person had already obtained a transition supply and the claim is rejected, the reject message to the Participating Pharmacy will explain the reason. Messaging examples are provided below.

At retail, Covered Persons are allowed at least a 30-day transitional supply of a non-formulary drug or a drug subject to certain limits. LTC Covered Persons are allowed up to a 31-day transitional supply per fill to allow a maximum of at least 98-days' supply with multiple fills, during their transition period. The 98-days' supply maximum takes into consideration those drugs that require Short Cycle Dispensing. (Refer to section: "Medicare Short Cycle Dispensing LTC Guidelines and Procedures"). The exception to the days' supply limits are drugs packaged in such a way that they cannot be dispensed for fewer days than the benefit limit (for example, Lupron Depot Inj. 11.25 mg which is prepackaged in a 3-month supply).

Participating Pharmacies, including Extended Supply Network (ESN) and Mail Order pharmacies, must remember that they may get a reject message indicating that a Covered Person may not obtain more than the days' supply limits noted above. However, please refer to all messaging. A claim may require other corrections or override codes. This should be done prior to reducing the days' supply to accommodate the transition days' supply limit; the claim may allow benefits without doing so.

If the claim remains rejected after all other corrections or overrides have been completed, then action should be taken to resolve the transition days' supply reject indicated within the message.

#### **Partial Fills**

Since Covered Persons may have received a partial fill during their transition period, it is important to reference the message indicating days' supply remaining and check their history for the drug to see if you can provide the remainder of their transition supply.

For instance, in the retail setting a Covered Person may have received a 9-day transition supply. That Covered Person is still eligible for the remaining 21-days' supply under the transition benefit during the transition period. Important Notice —To meet CMS requirements, Covered Persons in their transition period must not leave the Pharmacy without their medications as a result of a days' supply limitation. Covered Persons who continue enrollment in a Medicare Part D Benefit Plan are eligible for a transition benefit within the first days of the new year. Prime will provide a transition process consistent with the transition process required for new enrollees beginning each new year or make a transition prior to the beginning of the new year.

#### **Status Alerts**

A primary goal of the transition process is to alert the Covered Person of the non-formulary status of their drug and/or if their drug is subject to PA, ST, and/or QL. In these cases, Prime will use standard NCPDP codes indicating the payment of a claim is due to the transition benefit. Pharmacists receiving these codes must communicate the information to the Covered Person and suggest that the Covered Person contact their Prescriber to switch to a Formulary Drug or request a Drug Formulary exception or PA. Covered Persons will receive a letter from the Benefit Sponsor notifying them how to proceed.

### Sample POS Messaging

Here are some examples of RETAIL POS messaging during the transition period:

- If the claim is rejecting because the days' supply being submitted is greater than the allowed days' supply for that drug during the transition period:
  - MAX OF 30DS DURING TRANSITION PERIOD. RESUBMIT W/LESSER DS. AUTH OR FORM ALT REQ. CALL 800.821.4795 IF NEW/RE-ENROLLEE."
- If the claim is rejecting because the Covered Person has already received a full or partial transition supply during their transition period:
  - AUTH OR FORM ALT REQ/NONFORM/UM MEDS. MAX 30 DAY SUPPLY IN TRANSITION PERIOD. (##) DAY SUPPLY REMAINS 1.800.821.4795."
- When there is a paid claim the NCPDP approved message code "004" will be returned indicating:
  - » "Filled in Transition Bnft."

Reasons for and examples of LTC POS messaging during the transition period:

- If the claim is rejecting because the days' supply being submitted is greater than the allowed days' supply for that drug during the transition period:
  - MAX OF 31 DS/FILL IN TRANSITION PERIOD. RESUBMIT W/LESSER DS. AUTH OR FORM ALT REQ. CALL 800.821.4795 IF NEW/RE-ENROLLEE."
- If the claim is rejecting because the Covered Person has already received a full or partial transition supply during their transition period:
  - AUTH OR FORM ALT REQ/NONFORM/UM MEDS. MAX 98 DAY SUPPLY IN TRANSITION PERIOD. (##) DAY SUPPLY REMAINS. 1.800.821.4795."
- When there is a paid claim the NCPDP approved message code "004" will be returned indicating:
  - > "Filled in Transition Bnft."

There are additional benefits that apply to Covered Persons transitioning to/from LTC as well. They include the following:

- The level of care change benefit applies to Covered Persons who switch care settings from LTC to retail or from retail to LTC. Early refill edits are not used to limit appropriate and necessary access to their Part D benefit. Such Covered Persons are allowed to access a refill upon admission or discharge. When there is a paid claim due to the level of care change transition benefit, the NCPDP approved message code "012" will be returned indicating:
  - > "Level of Care Change."
- The emergency transition benefit applies to Covered Persons in the LTC setting.
- The emergency transition benefit allows up to a 31-day supply of Part D drugs that would otherwise reject non-formulary or be subject to certain limits. When there is a paid claim due to the emergency transition benefit NCPDP approved message code "008" will be returned indicating:
  - » "Emergency Fill Situation."

Refer to **Prime's Website** for Drug Formulary listings.

**Covered Persons in transition must leave the pharmacy with the appropriate medications.** If you have questions regarding the transition process or claims processing, please contact Prime's Contact Center at **800.821.4795.** 

# Medicare General Dispensing LTC Guidelines and Procedures

Participating Pharmacies that provide Prescription Drug Services to Covered Persons in an LTC facility must be familiar with the following guidelines:

- Claims must be billed in 31-day increments no more than once per month unless the claim meets the Short Cycle Dispensing requirements.
- Seven-day unit packages must be logged and billed no more than once per month.
- OTC products must be dispensed in the original container, and may not be priced higher than the shelf price.
- Items that are normally supplied by the LTC facility on a per-diem basis, such as test strips and syringes, are not billable to Prime.

- Unique dispensing methods (such as tray changes every two or seven days) do not justify additional dispensing fees. One dispensing fee per month is reimbursable except when the product is delivered to an LTC facility.
- If providing Prescription Drug Services to Covered Persons residing in an LTC facility, the Participating Pharmacy shall maintain a delivery log to acknowledge delivery. The delivery log should include:
  - > The Prescription number
  - > Date of fill
  - Delivery date and signature of Covered Person(s) receiving medication
  - Receipts and other documentation showing the Copay (if applicable) was paid by the Covered Person or their representative

For the most up-to-date processing requirements for LTC, please visit **Prime's Website**.

### Medicare Short Cycle Dispensing LTC Guidelines and Procedures

Participating Pharmacies servicing LTC facilities must dispense solid oral doses of brand-name drugs to Medicare Covered Persons residing in LTC facilities in no greater than 14-day increments at a time in accordance with 42 CFR §423.154. Prime will reject LTC facility claims that are submitted with invalid or missing Short Cycle Claim (SCC) combinations.

The following fields must be submitted on all LTC SCCs:

- NCPDP Field 147-U7 Pharmacy Service Type
- NCPDP Field 307-C7 Place of Service
- NCPDP Field 384-4X Patient Residence
- NCPDP Field 997-G2 CMS Part D Defined Qualified Facility

Please visit **Prime's Website** for detailed processing requirements.

# Section 5: Responsibility of Participating Pharmacy

## Update Information with NCPDP

The National Council for Prescription Drug Programs (NCPDP) requires that Participating Pharmacies submit pharmacy information updates to NCPDP directly as soon as the Participating Pharmacies are aware of them. To submit additions, changes, deletions, current address, fax number or phone number, go to NCPDP's website at **NCPDPOnline.org**.

Prime receives and incorporates weekly NCPDP updates into Prime's system, which include changes to a Participating Pharmacy address, fax number, phone number and Pharmacy Chain/Pharmacy Service Administration Organization (PSAO) affiliation. Prime's system supports only one PSAO affiliation at this time.

In order to ensure the integrity of Prime's data for Covered Persons to locate Participating Pharmacies, it is the Participating Pharmacy's responsibility to contact NCPDP within seven (7) business days when information changes.

## OIG/GSA Exclusion Checks

CMS requires that all individuals and businesses that contract to provide Medicare Prescription Drug Services make sure that everyone they employ is eligible to receive federal funds. Prime does not pay (either directly or indirectly) any individual or entity who has been excluded, suspended, or otherwise declared ineligible from participating in any state or federal health care program (e.g. Medicare, Medicaid, etc.).

A Participating Pharmacy has an obligation to make sure it does not employ, or contract with, any individual or business that is excluded or debarred from participation in Medicare or state health care programs. As required, exclusion checks must be conducted prior to contracting or hiring and monthly thereafter. If a Participating Pharmacy or a specific Participating Pharmacy location is sanctioned by the OIG and excluded from participation in federal health care programs, the Participating Pharmacy must notify Prime immediately. Please see the following sources for more information:

- Office of the Inspector General (OIG) website
- General Services Administration (GSA) website
- System for Awards Management (SAM) website
- CMS Prescription Drug Benefit Manual, Chapter 9

# Participating Pharmacy's Affiliation with PSAO

For a copy of Prime's Pharmacy Participation Agreement, a Participating Pharmacy should contact their PSAO.

Participating Pharmacies must notify NCPDP immediately upon change of affiliations with a PSAO. Under no circumstances shall Prime be liable for any losses suffered by Pharmacy as a result of inaccurate, incomplete, or other misinformation conveyed to Prime via the regularly received NCPDP interfaces.

On a weekly basis, the PSAO is required to provide Prime a list of pharmacies it intends to add to its organization. This information must be provided to Prime at least one (1) week before the effective date of the Participating Pharmacy's affiliation with the PSAO. The following information is required:

- PSAO affiliation code
- Participating Pharmacy NCPDP, name, address, and fax number
- Participating Pharmacy ownership information (including name of registered owner or owner group and ownership interest)
- Name of Pharmacist in Charge
- Name of any other staff pharmacists employed by the Participating Pharmacy
- Participating Pharmacy type (i.e. retail, compounding, etc.) and
- The effective date of the PSAO and Participating Pharmacy affiliation

## Section 5: Responsibility of Participating Pharmacy (Continued)

### Third Party Payment Reconciliation Company

Participating Pharmacies must update the EFT and 835 health care electronic remittance advice forms located on **Prime's Website** upon using a Reconciliation Company for the first time or upon changing its Reconciliation Company. Failure to do so can result in a violation of the Health Insurance Portability and Accountability Act (HIPAA).

### **Re-creation Fee**

In the event Participating Pharmacy, or Reconciliation Company, requests that Prime resubmit a properly submitted remittance advice, Prime may charge the Participating Pharmacy a re-creation and resubmission fee ("Re-creation Fee") in the amount of fifty dollars (\$50.00). Prime shall separately invoice Participating Pharmacy for all applicable Re-Creation Fees which shall be due 30 days from the date of invoice.

### Responsibilities of the Participating Pharmacy for Medicare Programs

In order to ensure compliance with CMS regulations, Participating Pharmacies in Prime's Medicare Network(s) must adhere to the guidelines outlined on Exhibit C(s) — Prime's Medicare Networks, which is part of Prime's Pharmacy Participation Agreement. A copy of minimum performance and service criteria for Prime's Medicare Networks is available on **Prime's Website**.

CMS requires retail and mail pharmacies to obtain patient consent to deliver a prescription, new or refill, prior to each delivery. This helps control FWA as required by 42 CFR § 423.504, and ensures that Medicare Covered Persons only receive new prescriptions and refills as requested. CMS and Medicare Part D Benefit Sponsors receive many consumer complaints of unneeded prescriptions being sent as part of auto-ship refill programs.

This does not apply to retail or LTC Participating Pharmacies that have refill reminder programs that require the Covered Person to pick up the prescription. Participating Pharmacies are required (when instructed through POS messaging) to include a copy of the "Medicare Prescription Drug Coverage and Your Rights" document with the Covered Person's prescription order. To print a copy of this CMS-required document (in **English** or **Spanish**), please visit **Prime's Website**.

Participating Pharmacies shall comply with CMS' Medicare Marketing Guidelines, when applicable. If Prime or a Benefit Sponsor identifies a communication that does not comply with CMS' Medicare Marketing Guidelines, Participating Pharmacies must cooperate with the removal or revision of the communication.

## Pharmacy Credentialing

Prime credentials pharmacies prior to entry into Prime's Pharmacy Networks. A new pharmacy must complete a credentialing exhibit and supply all of the supporting documents so Prime can review and process the application. Prime re-credentials all Participating Pharmacies at least once every three years in accordance with applicable law and contractual obligations. Prime follows non-discriminatory practices in the credentialing process. Participation in Prime's Network(s) is not based on factors such as race, religion, gender/gender identity, color, national origin, age and sexual orientation.

Re-credentialing is a requirement for continued participation in Prime's Pharmacy Networks. Failure to complete the re-credentialing exhibit will be cause for termination.

All Participating Pharmacies must provide Prime with copies of the following documents on an annual basis:

- Pharmacy License
- Pharmacist In Charge License
- DEA Certificate
- Certificate of Insurance with proof of General and Professional Liability Insurance

Participating Pharmacies must include their pharmacy name and NCPDP number on each of the documents.

## Section 5: Responsibility of Participating Pharmacy (Continued)

Participating Pharmacies must continue to meet Prime's credentialing criteria, which are determined at Prime's sole discretion. These criteria include, but are not limited to, Prime's billing thresholds for compound prescriptions drugs and non-FDA approved drugs.

## Signature or Delivery Logs

The Pharmacy shall ensure that all Covered Persons (or his or her authorized agent) who receive a Prescription Drug Service signs the signature or delivery log, acknowledging the date the Prescription Drug Service was received and the applicable prescription number. Prime may request signature and/or delivery logs for Prescription Drug Service(s) at anytime.

### Long-Term Care (LTC) and Home Infusion (HI) Annual Validation Process

In order for Prime to maintain the integrity of our HI and LTC Pharmacy Networks, Prime requires each Participating Pharmacy that participates in these Pharmacy Networks to annually validate that they are able to comply with guidelines outlined for participation in the HI and/or LTC Pharmacy Networks.

For your convenience, the validation forms are available on **Prime's Website** along with required guidelines for participation in the HI and LTC Pharmacy Networks.

Failure to validate may result in termination from the HI or LTC Pharmacy Networks.

### Termination Appeals

Participating Pharmacies have thirty (30) days from the date of notification of termination or an extended time as required by law to submit a termination appeal. Appeals must be submitted in writing and include the Participating Pharmacy's name and an explanation of the appeal. Terminations will be deemed finalized if an appeal is not received by Participating Pharmacy within the thirty (30) days from the date of notification of the termination or an extended time frame as required by law. Pharmacy termination appeals must be submitted in writing to the Pharmacy Network Contracting Department by fax at **877.823.6373** or by email to:

### PharmacyOps@PrimeTherapeutics.com.

A Participating Pharmacy that has been terminated from Prime's Pharmacy Networks may reapply one (1) year after the effective date of their termination.

Prime reserves the right to terminate a Participating Pharmacy from Prime's Pharmacy Network(s) for up to five (5) years, depending on the reason for termination.

## Confidentiality and Proprietary Rights

### Confidentiality

Any information or data obtained from, or provided by, Prime or any Benefit Sponsor to the Participating Pharmacy is confidential. This includes, but is not limited to, products, programs, services, business practices, procedures, MAC lists or other information acquired from the contents of the Pharmacy Participation Agreement, Provider Manual and related Exhibits or other Prime documents.

- The Participating Pharmacy shall not sell, assign, transfer or give such information to any third party without the prior written consent of Prime.
- No information or data obtained from or provided by Prime to the Participating Pharmacy may be quoted or attributed to the Participating Pharmacy or Prime without the prior written consent of Prime.
- The Participating Pharmacy must use all necessary security procedures to ensure protection of any information or data records from improper access.

## Section 5: Responsibility of Participating Pharmacy (Continued)

- The Participating Pharmacy must maintain the confidentiality of a Covered Person's personal profile and records including Protected Health Information (PHI) as required by applicable law, including state privacy laws and the Health Insurance Portability and Accountability Act of 1996 as amended. The Participating Pharmacy may not use the information provided by Covered Persons or any information obtained through performance of the Agreement for any purpose not related to the Agreement, except to the extent such use is required by applicable law and must establish privacy and security safeguards as appropriate and necessary.
- The Participating Pharmacy must promptly notify Prime if it becomes aware of any unauthorized use of Confidential Information or data.

#### **Proprietary Rights**

Except as required to fulfill the Participating Pharmacy's obligations under the Agreement, the Participating Pharmacy has no right to use, reproduce or adapt any information, data, work, compilation, computer programs, manual process or invention obtained from, provided by, or owned by Prime and/or Benefit Sponsor (including, but not limited to, products, programs, services, business practices and procedures) without Prime's prior written consent.

Prime has the right to disclose, use, reproduce and/ or adapt any information or data obtained from the Participating Pharmacy in any manner deemed appropriate, even if such use is outside the scope of the Pharmacy Participation Agreement, provided such use is in accordance with applicable law.

## Section 6: Participating Pharmacy Oversight

## Oversights

Oversight of Participating Pharmacies is a critical component of responsible pharmacy benefit management. Prime manages a robust pharmacy oversight program to detect inaccurate payments, drug waste, and fraudulent claims or other benefit coverage abuses. As part of this program, Prime regularly samples and reviews claims submitted by Participating Pharmacies in our Networks.

Prime conducts claim audits, onsite audits, and investigations ("oversight activities") to monitor compliance with state and federal regulations, Prime's Pharmacy Participation Agreements and this Manual. These activities verify the integrity of claims submitted to Prime and payments made to Participating Pharmacies. Prime's oversight activities also confirm the accuracy of the claim information submitted to Prime in order to identify instances of potential FWA.

Oversight activities comply with federal and state laws to ensure privacy and confidentiality of all patient records. Oversight activities also comply with Health Insurance Portability and Accountability Act (HIPAA) guidelines related to disclosure for treatment, payment or health care operations.

Findings related to Prime's oversight activities of Participating Pharmacies may result in pharmacy payment recoupment, claim adjustment, remediation and/or termination of the Pharmacy Participation Agreement. For purposes of the Participating Pharmacy Oversight section, please see the specific criteria found in the guidelines located in the Pharmacy Audit section on **Prime's Website**.

### Education

Prime may provide information to Participating Pharmacies via a Prime Audit Advisor Fax Blast and via the Prime Perspective newsletter. These documents may serve as a tool for Participating Pharmacies to use to strengthen documentation and billing practices, prepare for Prime audits, respond to Prime Investigations and reduce common billing errors.

## Access to Pharmacy Records

Participating Pharmacies must provide Prime with adequate access to their records related to Prescription Drug Services provided under the Agreement. This includes, but is not limited to:

- Wholesaler invoices and pedigrees
- Prescription orders
- Signature log/delivery log
- Licensing
- Proof of insurance
- Dispensing history

Prime reviews these records to compare the submitted claim information to the original source documentation, such as the prescription order and other relevant documentation to confirm the accuracy and legitimacy of the claim submitted to Prime.

If a Participating Pharmacy does not provide Prime access to requested documentation, facilities and/or personnel, a full recovery of any unverified claims may be assessed.

Participating Pharmacies shall not photograph or record (either audio or video) interactions with Prime personnel, including telephone discussions, onsite audits, or other interactions without Prime's prior written consent. Such activity may result in termination of the Pharmacy Participation Agreement.

### Expenses

Participating Pharmacies may not charge Prime for pharmacy personnel time involved in responding to Prime's oversight activities. Each Participating Pharmacy is responsible for its own expenses, including production of any records to Prime.

## Section 6: Participating Pharmacy Oversight (Continued)

### **Prescription Requirements**

"Prescription Hard Copies" means written prescriptions, refill authorizations, institutional orders, verbal or telephoned orders, facsimile orders, prescription transfers, and electronic prescriptions relied on by the Participating Pharmacy at the time of dispensing. To qualify as an electronic prescription, the electronic prescription must be noted prior to dispensing and have a system assigned user, date and time stamp to take the place of hard copy documentation.

The Participating Pharmacy must retain all documentation related to a prescription claim in accordance with the Pharmacy Participation Agreement and applicable state and federal laws. Prescriptions or claims that do not comply with state and federal regulations may be subjected to payment recovery.

A prescription is considered valid when the original prescription order contains the following information at the time of dispensing:

- Full name, address and date of birth of the Covered Person
- Date of Issuance
- Full name, NPI, and telephone number of the Prescriber and, if the prescription is for a controlled substance, the Prescriber's DEA number. If the Prescriber did not include their NPI/DEA number(s) on the prescription hard copy, then the pharmacy is responsible for acquiring the Prescriber ID either from the pharmacy's claim system or by contacting the Prescriber.
- The Participating Pharmacy must document correct Prescriber ID on the prescription hard copy or on a prescription label, affixed to the back of the prescription hard copy.
- Name of medication and strength prescribed
- Quantity authorized by the Prescriber
- **Specific Dosage change** The medication dispensed to the Covered Person must be labeled with the Prescriber's direction for use. The Participating Pharmacy must obtain specific directions for use to accurately dispense the prescription. Specific directions for "Use as Directed" are required. The

directions "As Directed" is not allowed. Directions may be obtained through direct communication with the Prescriber or, if the Prescriber is unavailable, the Covered Person. Directions must be documented on the prescription hard copy. The medication dispensed to the Covered Person must be labeled with the specific directions for use obtained from the Prescriber at the time of dispensing. For drugs that are administrated on a sliding scale, such as insulin, the Participating Pharmacy must obtain and document the dosage range or maximum per day prior to dispensing.

- Substitution instructions with appropriate documentation — When medically necessary, the Prescriber may write "Dispense as Written" on the prescription, or in the case of a telephoned prescription order, the pharmacist must write "Dispense as Written" on the telephoned prescription order. If a Covered Person requests a brand-name drug, the Participating Pharmacy must document the request on the prescription order.
- **Refill instructions** If there are no refills indicated by the Prescriber, the Participating Pharmacy should assume that there are no refills. If refills are added to a prescription, the Participating Pharmacy must retain written documentation of the authorization and assign a new prescription number.
- **Prescription Number**—The prescription hard copy must be labeled with the corresponding prescription number. If the prescription is for a drug under a federally regulated program (for example, iPledge, or S.T.E.P.S. Data 2000), the Participating Pharmacy must document the authorization number obtained from the program on the prescription hardcopy before dispensing.
- Documentation of the date the prescription was received and the name of the caller for verbal or telephoned prescription orders or clarification to any order
- Prescription hardcopies missing one or more of the required elements may be considered invalid and subject to audit or investigation recovery

## Section 6: Participating Pharmacy Oversight (Continued)

### Prescription Label Requirements

The prescription label must contain the following elements, in addition to other elements required by state and federal guideline:

- Full name of Covered Person Full name of Prescriber
- Full name and strength of medication dispensed
- Quantity of medication dispensed
- Specific directions for use
- Prescription number
- Number of refills authorized
- Date medication was dispensed

### Drug and Supply Requirements

Participating Pharmacies must purchase all medications and supplies being dispensed to Covered Persons from authorized traders, in accordance with Federal Law. The ordering of these medications and supplies must be tracked using verifiable invoices and pedigree invoices when required by applicable law. Prime reserves the right to not accept documentation from any authorized traders at any time when the invoice documentation cannot be verified.

## Wholesaler Invoices and Pedigrees

Prime my request that a Participating Pharmacy authorize their wholesaler(s) or manufacturer(s) to submit invoices and/or pedigrees to verify purchase and demonstrate that the medications were purchased from a legitimate source. Participating Pharmacies are responsible for validating that each of its own wholesalers has valid pedigree documentation.

### Distributor and Manufacturer Invoices and Pharmacy Dispensing Records

To prove that the drugs dispensed were purchased from an authorized source, Prime may request that the Participating Pharmacy authorize the wholesaler or manufacturer to release invoices and/or Pedigrees for purchase verifications. The Participating Pharmacy must promptly comply with such requests. Prime has the right to assess a full recovery of the amount paid for any claims in question. Wholesaler invoices received from the wholesaler must be verifiable and shall include Pedigree documentation upon request

### Review of Claim Submission

Prime will, at a minimum, verify the following claim elements when evaluating a prescription:

- **Covered Person** The prescription must contain the full name of the covered person and the correct Covered Person Identification Card number.
- **Date of Issuance**—The date of issuance must be present on the prescription.
- Drug name and Strength The NDC on the claim must correspond with the specific drug and strength prescribed and dispensed. Reasonable efforts must be made to select the most cost-effective form of the prescribed drugs or its generic equivalent.
- NDC The NDC on the claim must correspond to the NDC used to dispense the prescription.
- **Price**—The accuracy of the calculating and submitting price is based on the NDC's and quantities used to dispense the product.
- **Product Selection Code (PSC)** PSC submissions will be verified. If the Participating Pharmacy submits a DAW-1 and no written substitution directive is present on the prescription, the claim(s) will be subject to recovery. When the Covered Person requests the brand-name drug, the Participating Pharmacy must document the Covered Person's request on the original hard copy and submit the claim with a DAW-2. If the generic is not available to the market, the Participating Pharmacy must document on the original hard copy and submit the claim with a DAW-8.

- **Quantity**—The Participating Pharmacy must dispense the quantity as written and supported by the dosing directions unless the quantity written exceeds the Covered Person's benefit, the quantity written is for greater than the amount needed for the timeframe needed based on use instructions (i.e. writing for 20 doses per month when directions are to infuse 3 times weekly) or unless the quantity written is intended to be dispensed only if certain situations occur (i.e. hemophilia bleed dose replacement upon submission of infusion records). The Participating Pharmacy must comply with POS messaging, including but not limited to, messaging regarding the Covered Person's benefit limit and must document the reason for dispensing a lesser quantity on the original prescription. If the POS messaging on the claim requires a PA, the Participating Pharmacy must follow POS messaging and not reduce the quantity. To prompt accurate POS messaging, the Participating Pharmacy must accurately represent the days' supply based on the quantity dispensed and directions for use on the prescription order.
- Days' Supply The Participating Pharmacy must submit the correct days' supply, based upon directions for use. The Participating Pharmacy must submit the number of consecutive days the prescription drug will last. Overstating the days' supply may affect future refills, while understating the days' supply may exceed the Covered Person's benefit. The most common days' supply errors occur when dispensing inhalers, insulin and medication with intermittent dosing. A Participating Pharmacy is responsible for submitting the correct days' supply based on the quantity dispensed and the directions of use on the prescription order. For examples of medications commonly billed erroneously, visit **Prime's Website**.
- **Refill Instructions** Refill history will be reviewed to assure that the prescription was not refilled in excess of the prescription order. If additional refills are authorized, the Participating Pharmacy must obtain the appropriate prescription order based on the drug class.

- Auto-Ship refills Prime requires Participating Pharmacies to obtain patient consent prior to enrolling a prescription in auto-ship refill programs. This is to control FWA and ensure Prime's Covered Persons only receive new prescriptions and refills as requested.
- Claim edits If the Participating Pharmacy receives specific messaging when a claim is submitted, the Participating Pharmacy must ensure that documentation is maintained to support the use of dynamic PA (override or DUR override) numbers or clarification code. Inappropriate use or lack of supporting documentation related to the dynamic PAs or clarification codes will be subject to audit recovery.
- **Prescriber ID number** The Participating Pharmacy must enter the correct Prescriber's ID number on the claim submission. Claims submitted under the wrong Prescriber ID number or an invalid Prescriber ID number may result in the pharmacy being placed on a corrective action plan.
- Usual and Customary (U&C) The Participating
   Pharmacy will submit the lowest price the Participating
   Pharmacy would charge a customer that was paying
   cash for the identical Prescription Drug Services on the
   date dispensed. This includes any applicable discounts
   including, but not limited to, senior discounts, frequent
   shopper discounts, coupons, discount card programs
   and other special discounts used to attract customers.

Discrepancies between the claim submission and the original prescription order may result in a full or partial recovery of the amount paid or other remediation, as determined in Prime's sole discretion.

### Common Billing Errors

 Quantity Dispensed — Overstating the days' supply may affect future refills. Understating the days' supply may exceed the Covered Person's benefit, while assessing less copay that is applicable. The Participating Pharmacy must submit the correct days' supply, based on directions for use and benefit limitations to avoid an audit recovery (for example, incorrectly calculating the days' supply for eye drops. Calculate eye drops days' supply using 15 drops per mL for solutions and 12 drops per mL for suspensions).

- **Reversal of claims**—All prescriptions not received by the Covered Person within fourteen (14) days of claim submission must be reversed through the electronic claim system. Claims not reversed after fourteen (14) days may be subject to audit recovery.
- Use as Directed The Participating Pharmacy must determine the specific dosing directions to accurately calculate the days' supply and correctly submit the claim to Prime. The participating Pharmacy must contact the Prescriber to clarify any ambiguous directions (such as "Use as Directed," no directions documented or "As needed") and document them on the prescription hardcopy. If the Prescriber is unavailable, communication with the Covered Person is acceptable and must be documented.
- One prescription for the entire family Prescriptions written for an entire family on one prescription form must be processed as separate claims for each Covered Person.

For examples of medications commonly misbilled medications, visit **Prime's Website**.

### Unacceptable Billing Practices

Based on the claim submission requirements, the following are examples of unacceptable and, in some cases, fraudulent practices which may be subject to a full or partial recovery of the amount paid or other remediation, including but not limited to:

- Billing for a legend or OTC drug without a prescription or benefit-sponsored voucher.
- Submitting incorrect information on claims that may lead to inappropriate bypass of benefit exclusions, DUR messages, or other Benefit Plan edits.
- Billing for a quantity of a legend drug that is different than the quantity prescribed
- Billing for a higher priced drug when a lower priced drug was prescribed and/or dispensed
- Dispensing a generic drug but billing for the brand name drug.
- Submitting claims with an NDC other than the DNC from the package from which the product was dispensed.

- For general LTC dispensing, billing more than once per month for Federal Legend Drugs for Covered Persons in an LTC Facility where short-cycle dispensing is not allowed.
- Dispensing drugs that are solid oral dose brand-name drugs in greater than 14-day increments for short cycle dispensing.
- Overriding DUR rejects without properly resolving and documenting the resolution.
- Incorrectly billing Medicare Part A or Part B eligible drugs to a Medicare Part D
- Billing compound products in a manner inconsistent with Prime's credentialing criteria and/or the compound billing requirements described in the Compound Drugs Billing Guidelines of this Manual.
- Applying an expiration date on the prescription order that is earlier than the date the product expires according to the manufacturer
- Misrepresenting the U&C
- Billing the Covered Person for any associated recovery.
- Misrepresenting the origin code
- Billing for drugs that were never purchased by the Participating Pharmacy
- Billing for drugs associated with wholesaler invoices that the respective wholesaler denies providing to the pharmacy because the drugs were not purchased from the wholesaler.
- Billing for drugs from a wholesaler that cannot provide drug ancestry or pedigree documentation supporting the legitimate purchase record of the drug.
- Submitting a claim for a non-FDA approved drug (such as compound kits and patches).
- Billing greater vial size than what is necessary to supply the ordered dose.
- Billing high cost products when lower cost alternative products are available.

Participating Pharmacies may not solicit Covered Persons or obtain a third party to solicit Covered Persons to obtain prescription orders.

### **Recovery of Pharmacy Payments**

Prime will collect improper payments paid to Participating Pharmacies in a manner determined by Prime. Pharmacies will be informed of payment off-sets through the standard remittance advice. Pharmacies will receive a report of claim adjustments performed directly by Prime.

### Reasons for Audits

Several situations could trigger an audit. These situations include but are not limited to:

- Request or inquiry by a Benefit Sponsor, Covered Person or government agency Pharmacy billing history
- Pharmacy does not respond to Prime's requests for documentation.
- Prime identifies billing issues through the claim audits.
- Referral from Prime's FWA Hotline or other sources that indicate potential FWA
- Routine audit of pharmacies selected on a random basis

### Audit Time Frame

Claims selected for audit through the daily claim audit process generally include prescriptions billed to Prime within the previous fourteen (14) days. Historical claim audits generally include prescriptions billed to Prime within the previous twelve (12) months. Standard onsite audits generally include prescriptions billed to Prime within the previous twenty-four (24) months. However, Prime has the right to audit and/or investigate claims for up to seven (7) years from the date of the Prescription Drug Service for commercial claims, and up to ten (10) years from the date of Prescription Drug Service for government program claims, or as otherwise permitted by law.

## Types of Audit Activities

### Daily and Historical Claim Audits

Prime monitors claims data to identify potential billing and compliance errors. When Prime identifies potential pharmacy errors shortly after adjudication, Prime contacts the Participating Pharmacy who is instructed to correct the claim. This process is intended to educate Participating Pharmacies on Prime's billing requirements and helps avoid retrospective audit recoveries. If the Participating Pharmacy does not respond to Prime's requests or fails to correct improperly billed claims, impacted claims may be resubmitted or reversed by Prime, in its sole discretion.

If a claim is identified for audit, Prime will contact the Participating Pharmacy via telephone, email or facsimile to inquire about the claim. Requested documentation may include, but is not limited to:

- Photocopies of the original prescription order, front and back
- Signature or delivery logs
- Receipts and other documentation showing the copay (if applicable) paid by the Covered Person or their representative
- Tracking number from delivery log, which must link to the prescription number and date of service that was delivered
- Computer records
- Wholesaler, manufacturer and/or return vendor invoices
- Pedigree invoices or documentation to confirm traceability of the medication from the manufacturer
- Compound information including all ingredients with NDC's and quantities used to prepare the compound claim
- Dispensing logs
- Bleed logs
- Prescription label
- Pharmacy and Pharmacist-in-Charge Liability Insurance
- Professional Insurance information

- Proof of FWA training
- License information
- Bill of Sale
- Documentation required as a standard industry practice to support appropriate dispensing of medications
- Attestation of compliance with specific state and/or federal statutes, regulation, or CMS guidance

If a Participating Pharmacy processes Long Term Care (LTC) Facility claims the following additional information may also be requested:

- Demographic information of any LTC facilities that were serviced by the Participating Pharmacy during the time frame of the audit and/or investigation
- Medication administration records of the Participating Pharmacy and/or the LTC Facility
- LTC Facility census information for the Covered Person during the audit and/or investigation that provides information on Medicare Part A stays

Prime will provide the Participating Pharmacy with a due date for submitting audit documentation. The Participating Pharmacy may either fax, mail or email copies of the requested documentation.

#### **Government Programs Fax:**

- 877.290.1516
- 866.466.7686

#### **Commercial Fax:**

- 877.825.7404
- 877.263.5543

#### Email: pharmacyaudit@PrimeTherapeutics.com

If you suspect FWA involving the Federal Employees Plan by a covered person, prescribing provider, participating pharmacy or anyone else, notify Prime:

### Phone: 844.765.9990

#### Email: FEPreportfraud@PrimeTherapeutics.com

Mailing Address:

### Prime Therapeutics LLC ATTN: Pharmacy Audit P.O. Box 64812, St. Paul, MN 55164-0812

A Participating Pharmacy's failure to submit the requested documentation by the due date may result in:

- Full or partial recovery of the amount paid on impacted claims
- Escalation to an on-site audit
- Termination of the Pharmacy Participation Agreement

Late fees may apply if the Participating Pharmacy does not provide complete and timely documentation to missing or late audit documentation.

A Prime auditor will review the requested claims to verify that the claims have been submitted in compliance with the Pharmacy Participation Agreement and Prime Provider Manual. Participating Pharmacies will receive a claim adjustment report for those claims adjusted directly by Prime.

### **Onsite Audits**

Participating Pharmacies selected for onsite audit may receive advanced written notice from Prime. Advance notice may not be provided at Prime's discretion, as allowed by law. If Participating Pharmacies cannot accommodate an onsite audit on the scheduled date and previous arrangements have not been agreed to by Prime, Prime reserves the right to assess a full recovery of any unverified claims.

Onsite audits are conducted during regular business hours. Prime makes reasonable efforts to minimize disruption to all areas of the Participating Pharmacy. Participating Pharmacies are expected to provide Prime with access to the pharmacy and the documentation to support the claims submitted during the audit period should be readily retrievable and accessible.

Participating Pharmacies are also expected to be adequately staffed during the audit and to have a representative (either pharmacist or technician) available to respond to questions and retrieve specific prescription hard copies and supporting documentation that may be needed. While onsite, the auditor will observe the Participating Pharmacy practices and review all related documentation. The auditor may request to observe the Pharmacy's dispensing practices, including review of prescriptions pending member pickup. An interview will be completed with pharmacy personnel, preferably with the Pharmacist-In-Charge (PIC).

Requested documentation may include, but is not limited to:

- Photocopies of the original prescription order, front and back
- Prescription label
- Signature or delivery logs
- Receipts and other documentation showing the copay (if applicable) paid by the Covered Person or their representative
- Tracking number from delivery log, which must link to the prescription number and date of service that was delivered
- Computer records
- Wholesaler, manufacturer and/or return vendor invoices
- Pedigree invoices or documentation to support wholesaler(s) purchases to confirm traceability of the medication from the manufacturer
- Compound information including all ingredients with NDC's and quantities used to prepare the compound claim Pharmacy and Pharmacist-in-Charge Liability Insurance
- Dispensing logs
- Bleed logs
- Professional insurance information License information
- Proof of annual FWA training
- Pharmacy Bill of Sale, if applicable

- Documentation required as a standard industry practice to support appropriate dispensing of medications
- Attestation of compliance with specific state and/or federal statutes, regulation, or CMS guidance

If a Participating Pharmacy processes Long Term Care (LTC) Facility claims the following additional information may also be requested:

- Demographic information of any LTC facilities that were serviced by the Participating Pharmacy during the time frame of the audit and/or investigation.
- Medication administration records of the Participating Pharmacy and/or the LTC Facility
- LTC Facility census information for the Covered Person during the audit and/or investigation that provides information on Medicare Part A stays.

Onsite audits will involve the disclosure of Covered Persons' Personal Health Information (PHI) for the purpose of disclosure of treatment, payment or health care operations. For Prime and the Participating Pharmacy to remain HIPAA compliant, a Pharmacy staff person is required to retrieve documentation; however, the auditor must be present to observe the documentation retrieval.

Participating Pharmacies may not refuse to comply with an onsite audit on the grounds that it violates HIPAA or other relevant privacy laws.

A Prime auditor will review the claims for accuracy and compliance with the Pharmacy Participation Agreement and this Manual.

Audit documentation, including prescriptions and supporting documentation, may be photographed or copies will be requested by the auditor as necessary.

When the audit is complete, the auditor will provide general feedback verbally while onsite at the Participating Pharmacy.

A Participating Pharmacy's failure to cooperate with an on-site audit may result in:

- Full or partial recovery of the amount paid for the related claims Termination of the Pharmacy Participation Agreement
- Other remedial action as determined by Prime

### Reporting Onsite Audit Results

Following the onsite audit, Prime will provide the Participating Pharmacy with a written preliminary audit report, which will include details of any discrepancies or relevant audit findings, as required by applicable law.

Results include details of any issues of non-compliance with:

- Federal and state regulations
- The Pharmacy Participation Agreement
- Prime's Provider Manual
- Discrepancies between the original prescription order documentation available at the time of dispensing and the Participating Pharmacy's claim submission

The Participating Pharmacy will be provided a date by which any additional documentation supporting the claims may be provided to Prime by the Participating Pharmacy. Prime will review additional documentation received. A final audit report will be issued to the Participating Pharmacy after review of the additional documentation received or after the due date to provide additional documentation has passed.

### **Onsite Audit Appeal Process**

Participating Pharmacies have thirty (30) days from the date of final audit report is issued by Prime to submit an appeal or an extended timeframe as required by law or regulation. Appeals must be submitted in writing and include the Participating Pharmacy's name, the claims/prescriptions being appealed, any additional documentation not provided at the time of audit and an explanation of the appeal. Please see the Pharmacy Audit Recovery Guidelines for post-audit documentation accepted by Prime. Audit findings, including associated recoveries, will be deemed finalized if an appeal is not received by the Participating Pharmacy within the thirty (30) days from the date of notification of the audit findings or an extended time frame as required by law or regulation. Documentation provided by the Participating Pharmacy as part of its audit appeal may result in additional findings. Appeal results are considered final. For a copy of Prime's Pharmacy Audit Appeal form and Prime's Audit Recovery Guidelines, visit Prime's Website.

### **Remediation Action**

Prime may take remediation action against a Participating Pharmacy as a result of audit performance, including but not limited to termination of the Pharmacy Participation Agreement, as determined in Prime's sole discretion. Prime may also apply either full or partial recovery of the amount paid for a specific claim. Recovery amounts are noted in the preliminary and final audit reports.

A Participating Pharmacy may be immediately terminated form Prime's Pharmacy Network(s) upon Prime's receipt of any evidence of a Participating Pharmacy engaging in activities that may result in FWA.

## Corrective Action Plan (CAP)

Participating Pharmacies may be placed on a corrective action plan, as determined by Prime in its sole discretion. Participating Pharmacies subject to a corrective action plan are monitored to determine whether the identified issues have been remediated. If issues are not resolved to the satisfaction of Prime, additional remedial action may be taken by Prime, as permitted by the Agreement. Failure to comply with the terms of the corrective action plan may result in termination of the Pharmacy Participation Agreement.

## Pharmacy Investigations

Prime may conduct an investigation of any Participating Pharmacy when Prime suspects or identifies potential FWA. During an investigation Prime may request access to the Participating Pharmacy's facilities, personnel and any supporting documentation to support claims submitted to Prime during the investigative time frame. Participating Pharmacies may not receive notification in advance of an onsite investigation. Timing of communications and reports to the Participating Pharmacy may vary. Prime will issue applicable reporting to the Pharmacy throughout the investigative process. Prime reserves the right to terminate all pharmacies under the same ownership or control the results on an investigation.

Failure to comply with an investigation conducted by Prime may result in full recovery if any claims subject to review and/or termination from Prime's Pharmacy network(s), as determined in Prime's sole discretion.

## Section 7: Medicaid Requirements

### General Medicaid Program Inquiries

For general inquiries related to the Medicaid Programs please call:

- BCBSMN Blue Plus: 800.821.4795
- BCBSIL Family Health Plan: 855.457.0173
- BCBSIL Community ICP: 888.274.5218
- BCBSNM Community Centennial: 855.699.0040
- BCBSTX Children's Health Insurance Program (CHIP): **855.457.0403**
- BCBSTX State of Texas Access Reform (STAR): 855.457.0405
- BCBSTX STAR Kids (Travis service area): 855.457.0757
- BCBSTX STAR Kids (MRSA Central service area): 855.457.0758

### General Medicaid Requirements

### **Pharmacy Disclosure Statement**

Participating Pharmacies who participate in Medicaid Programs must complete a Pharmacy Disclosure Statement to comply with federal and/or state regulations. Participating Pharmacies must complete Prime's Pharmacy Disclosure Statement when requested, and if there is any change in ownership, Participating Pharmacy must submit a new Pharmacy Disclosure Statement.

## Illinois Medicaid Requirements

### **Automatic Refills**

The use of automatic refills by Participating Pharmacies in Prime's Illinois Medicaid Network is not allowed. All Prescription Drug Services refills must be initiated by a request from the physician, Covered Person, or other person acting as an agent of the Covered Person, e.g., a family member. Any Prescription Drug Services with remaining authorized refills does not constitute a request to refill the prescription. The Illinois Department of Healthcare and Family Services (HFS) will not reimburse a Participating Pharmacy for any Prescription Drug Service that has been filled using an auto refill process. Any claim for a Prescription Drug Service filled without a request from the prescriber, Covered Person, or agent of the Covered Person will be subject to recovery. Claims for Prescription Drug Services that have been filled using auto refill and inadvertently billed to HFS must be reversed by the Participating Pharmacy.

### Minnesota Medicaid Requirements

### **Automatic Refills**

Minnesota Health Care Programs (MHCP) does not allow automatic refills for Medicaid members. The Participating Pharmacy may not contact the Covered Person to initiate a refill unless it is part of a good faith clinical effort to assess the Covered Person's medication regimen. Prescription refills are not eligible for payment without an explicit request from a Covered Person or authorized caregiver.

A Prescribing Provider or other authorized agent of a facility may initiate a request for refill for a Covered Person residing in a skilled nursing facility, group home, or assisted living arrangement.

### **Do Not Accept Cash Payment**

As a general reminder, Participating Pharmacies may not accept a cash payment from a Covered Person or from someone paying on behalf of the Covered Person, for any MHCP Prescription Drug Service.

A Participating Pharmacy may accept a cash payment for a non-covered prescription drug provided that:

- The Covered Person is not enrolled in the restricted Covered Person program.
- All available covered alternatives have been reviewed with the Covered Person.
- The Participating Pharmacy obtains a Covered Person signature on the MHCP Acknowledgment form.
- The prescription is not a controlled substance (except phentermine in certain circumstances) tramadol or gabapentin.

A Participating Pharmacy may only accept a cash payment for a controlled substance, tramadol or gabapentin, if the Pharmacy has received authorization from MHCP to do so on the date of service. To be considered for a cash payment authorization, the Prescribing Provider must contact the MHCP help desk at **800.366.5411** and explain why the covered alternatives are not viable options for the Covered Person. If a Covered Person's MHCP eligibility status is in question and the Covered Person offers a cash payment for Prescription Drug Services, the Participating Pharmacy must verify eligibility through Minnesota Information Technology Services (MN-ITS) or Eligibility Verification System (EVS). If the person does not have coverage through MHCP, a pharmacy can accept cash as payment.

### **Cash for Phentermine**

Participating Pharmacies may accept cash for phentermine prescription drug claims as advised by the MHCP. Phentermine is not covered by Medical Assistance because weight loss drugs are excluded from coverage pursuant to Minnesota state law.

A Participating Pharmacy may accept cash payment for a phentermine prescription drug provided that:

- The phentermine prescription drug is being used as part of a comprehensive weight loss program and is prescribed at the FDA-approved dosage.
- The Prescription Drug Monitoring Program has been reviewed and determined that the phentermine prescription drug is not being abused or overused.
- The Covered Person has been informed about the responsibility for payment before the phentermine prescription drug was dispensed.
- The Participating Pharmacy or an authorized health care representative completes the Advance Recipient Notice of Non-covered Prescription (DHS-3641) (PDF) and the Covered Person signed the form.

For further information on Minnesota's Medicaid regulations:

- Recipient Payment for Noncovered Prescriptions
- Pharmacy Services

If you have questions regarding claims processing, please call Prime's Contact Center at **800.821.4795**.

For further information on Minnesota's Medicaid regulations, visit **Minnesota Department of Human Services**.

### Texas Medicaid Requirements

Prime is the pharmacy benefit manager for Blue Cross and Blue Shield of Texas, a managed care plan that provides services for Covered Persons participating in the Texas Medicaid plans. The terms and conditions of this section titled "Texas Medicaid Requirements" shall apply to Participating Pharmacies that provide Prescription Drug Services to Covered Persons in the Texas Medicaid Network.

### National Provider Identifier (NPI)

The Participating Pharmacy must submit the Prescriber's NPI for all Medicaid claims.

### **Pharmacy Credentialing**

For entry into the Texas Medicaid Network, a pharmacy must fill out a credentialing application and provide the following documents:

- Pharmacy license number
- Pharmacist in Charge license number
- DEA Certificate
- Certificate of Insurance with proof of General and Professional Liability Insurance
- Pharmacy Disclosure Statement

Within fifteen (15) days of receiving a fully completed credentialing application from the pharmacy, Prime will assess and verify that the pharmacy name, pharmacists and the pharmacy owner are not excluded or debarred. Prime uses the **Texas State Board of Pharmacy website** as the primary source of validation to verify that all pharmacies and pharmacists' licenses are active, and no disciplinary actions exist on file. If a disciplinary action is found, Prime will conduct further assessment.

All Participating Pharmacies in the Texas Medicaid Network must provide Prime with the documents listed above on an annual basis.

### Documentation

Specific to the Texas Medicaid program, verbal changes and clarifications to the Prescriber's prescription order must be documented on the original hard copy or electronically noted in the Participating Pharmacy's online system prior to dispensing. The Participating Pharmacy will request the Prescriber obtain a PA. Electronic documentation must be noted prior to dispensing and must have a system assigned user, date and time stamp in order to take the place of hard copy documentation. When additional refills are ordered, a new prescription number must also be assigned and appropriately documented on a hard copy.

### **Compound Drugs Billing Guidelines**

Participating Pharmacies must submit compound drugs through the Prime POS system using the following directions:

- Flag the compound as a compound drug in the Participating Pharmacy's system prior to adjudication.
- Submit a zero (0) in the NDC portion of the claim using the compound segment.
- Enter the qualifier, NDC, quantity, cost and cost basis for each ingredient in the compound.
- Submit the final product quantity (the quantity of the finished compound product).
  - For a liquid, submit the number of mL of the finished compound product
  - For capsules, submit the total number of capsules being dispensed
  - For creams or ointments, submit the total number of grams being dispensed
- Submit the total ingredient cost, including OTC ingredients. For total ingredient cost, multiply the quantity used for the individual ingredient and the AWP for the individual ingredient according to the pricing source at the time of dispensing for each eligible ingredient used. Then, add all of the individual ingredient costs.
  - Plan-excluded drugs and invalid NDCs are not eligible for reimbursement

- Eligible OTC ingredients may be covered by the benefit plan
- > Eligible ingredient costs do not include costs for labor, equipment, professional fees or flavoring
- Maintain compound log documentation to document quantities and NDCs of the ingredients used to prepare the compound. NDCs submitted for the compound must be the exact formulation of what is dispensed in the compound.
- Prime will accept a multiple ingredient compound submission using NCPDP's compound segment for up to 25 ingredients.
- The Participating Pharmacy must submit the submission clarification code of "08" for all compounds to allow payment of all covered ingredients, including OTC products. The Participating Pharmacy must follow POS messaging to determine if the ingredients submitted requires a PA prior to submitting the "08" clarification code.

Participating Pharmacies are expected to observe applicable state and federal laws, relevant U.S. Pharmacopoeia (USP) Chapter Guidelines, professional standards and FDA communications when preparing and dispensing compound drugs. Evidence of unprofessional or unsafe compounding found during the pharmacy audit process or otherwise, may be reported to the applicable State Board of Pharmacy and/or the FDA, and may result in termination of your Pharmacy Participation Agreement.

The following are examples of compound drugs that benefit design may not cover:

- Modified-release compounds (based on Covered Person benefit design).
- Any compound that contains active ingredients not approved by the FDA.
- A compound for which the stability is unknown at the time of dispensing or cannot be determined by reference of an USP-approved reference material.
- Experimental/investigational items, products or services.

- Any finished product intended to address medical diagnosis (such as sugar-free products) where the Covered Person's medical diagnosis does not support the need for the finished product.
- Any compound that differs from the equivalent commercial form only by the addition of cosmetic agents or agents intended to produce a cosmetic effect.

The following drugs cannot be submitted to Prime as a compound drug:

- Reconstituted nonsterile products, to which only water, alcohol or sodium chloride solution are added to the active ingredient (for example, children's antibiotic suspensions).
- Any prescription that is subdivided into unit dose(s).
- Injectable drugs that are drawn into syringes for administration.
- Any compound that has an equivalent commercial form except in some limited situations in which the compound is preferred according to the Benefit Plan. This exception may vary by state.

Prime also considers the following additional to be unacceptable billing practices for compound drugs:

- Billing for a different NDC than what was used in the compound.
- Billing for the full package size when only a partial amount was dispensed to the patient.
- Billing for a different dosage form than what was used in the compound.
- Billing for a quantity other than what was actually used to prepare the compound.
- Any compound to which active ingredients are added that were not part of the prescription order.
- Not following POS messaging, including but not limited to messaging for rejected claims.
- Obtaining changes to prescription orders to avoid POS messaging.

- Billing claims in a manner that bypasses system messaging requiring further review.
  - Example: billing claims multiple times in a month to avoid obtaining a PA or reaching plan dollar thresholds

If you have questions regarding compound drugs please contact Prime's Contact Center as follows:

- STAR Covered Persons at 855.457.0405
- CHIP Covered Persons at 855.457.0403
- STAR Kids (in the Travis service area) at 855.457.0757
- STAR Kids (in the MRSA Central service area) at **855.457.0758**

### Maximum Allowable Cost (MAC) and Appeals

To place a drug on Prime's Texas Medicaid MAC list, the drug must be "A" or "B" rated in the most recent version of the United States Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book. The drug must also:

- Have an "NR" or "NA" rating or a similar rating by a nationally recognized reference.
- Be generally available for purchase by Participating Pharmacies in the state of Texas from national or regional wholesalers.
- Not be obsolete.

Prime's MAC pricing is reviewed a minimum of once every seven days. This ensures that the MAC price of every drug is based on the current market price of available therapeutically equivalent drugs. A Participating Pharmacy may challenge a listed MAC price for a drug by submitting an invoice and claim information of the MAC drug being appealed. Prime will respond to a challenge no later than the 15th day after the date the challenge is made. If the challenge is successful, the MAC price for the drug will be adjusted on the date the challenge is resolved, and will be applicable to all similarly situated Participating Pharmacies as determined by Prime. If the challenge is denied, Prime will provide a reason for the denial. If a Participating Pharmacy would like access to Prime's MAC lists, weekly MAC changes, MAC pricing appeals process, and the sources used to determine MAC pricing, please refer to **Prime's Website** for registration instructions. After network participation is verified, the participating network pharmacy provider will receive a secure user name and password via email to access Prime's MAC lists.

### **Prescription Drug Benefits**

Prime uses the Texas Vendor Drug Program Preferred Drug List.

### How to Use the Drug Formulary

The Drug Formulary lists the brand name and generic name of a given drug. If a medication does not appear on this Drug Formulary, the medication is not covered under the pharmacy benefit. In some instances, a medication may require a PA. A PA form should be completed by the Prescriber and submitted to Prime before the prescription may be filled.

To obtain the PA form for medications requiring PA, please contact Prime's Contact Center as follows:

- STAR Covered Persons at 855.457.0405
- CHIP Covered Persons at 855.457.0403
- STAR Kids (in the Travis service area) at 855.457.0757
- STAR Kids (in the MRSA Central service area) at **855.457.0758**

You may search the Drug Formulary at the **Texas Vendor Drug Program** or through **Epocrates**.

### **Prior Authorization (PA)**

PA is designed to encourage appropriate use of medications. Select medications may require a PA. Medication utilization must meet FDA-approved indications, as well as Prime's medical necessity guidelines. The Participating Pharmacy should not request changes to a prescription for the sole purpose of avoiding POS messaging. For example, if a Participating Pharmacy receives a POS message indicating a PA is required, or that it must call Prime's Contact Center, the Participating Pharmacy is expected to follow the POS messaging and Prime's Contact Center instructions. The Participating Pharmacy may contact the Prescribing Provider for further clarification or additional information about the prescription as needed. If a medication requires PA: a PA form should be completed by the Prescriber for submission to Prime.

To obtain a PA form, the Participating Pharmacy may contact Prime's Contact Center as follows:

- STAR Covered Persons at 855.457.0405
- CHIP/CHIP Covered Persons at 855.457.0403
- STAR Kids (in the Travis service area) at 855.457.0757
- STAR Kids (in the MRSA Central service area) at 855.457.0758
- CoverMyMeds

All PA fax forms may be submitted via fax to **877.243.6930** 

### **Emergency Prescription Supply**

A Participating Pharmacy will receive a rejection of "PA Required" for a non-preferred drug that has not been prior authorized. The message will indicate that the drug is non-preferred and that the Prescriber should call Prime's PA line at **855.457.0407** to initiate a PA request.

If the Participating Pharmacy is unable to override, simply call Prime's Contact Center—available 24 hours/7 days a week—for assistance:

- STAR Pharmacy Contact Center at 855.457.0405
- CHIP Pharmacy Contact Center at 855.457.0403

- STAR Kids (in the Travis service area) Pharmacy Contact Center at **855.457.0757**
- STAR Kids (in the MRSA Central service area) Pharmacy Contact Center at **855.457.0758**

In emergency situations, after hours or on weekends, Participating Pharmacies are authorized to dispense a 72-hour emergency supply of any non-preferred medication without prior approval. Participating Pharmacies should submit an "8" in field 461 EU (PA Type Code) and code "801" in field 462 EV (PA Number Submitted), and a "3" in Field 404 D5 'Days Supply' in the claim segment of the billing transaction. The quantity dispensed and submitted in Field 442 E7 "Quantity Dispensed" should equal the quantity necessary for a 3-day supply according to the directions for administration given by the Prescriber.

A 72-hour emergency supply of a prescribed drug must be provided when a medication is needed without delay and PA is not available. This applies to all drugs requiring a PA, either because they are non-preferred drugs on the Preferred Drug List or because they are subject to clinical edits. However, it does not apply to hepatitis C drugs or any drug not considered to be an emergency in the judgment of the dispensing pharmacist.

The 72-hour emergency supply should be dispensed any time a PA cannot be resolved within 24 hours for a medication on the Vendor Drug Program formulary that is appropriate for the member's medical condition and where delay could cause harm. If the Prescriber cannot be reached or is unable to request a PA, the Participating Pharmacy should submit an emergency 72-hour prescription.

A Participating Pharmacy can dispense a product that is packaged in a dosage form that is fixed and unbreakable, e.g., an albuterol inhaler, as a 72-hour emergency supply. The 72-hour emergency supply is not applicable if PA denial is on record.

### **Quantity Supply Limits**

BCBSTX allows up to a 34-days' supply of medication. This program defines a standard 34-days' supply of medication for a select list of medications. If a medical condition warrants a greater quantity supply than the defined 34days' supply of medication, a PA will ensure access to the prescribed quantity. Prior to dispensing, a PA needs to be submitted to Prime to determine medical necessity.

### **Dose Optimization**

The Dose Optimization Program, or dose consolidation, is an extension to the quantity supply program, which helps increase patient adherence with drug therapies. This program works with the Covered Person, the Covered Person's physician or health care provider and the pharmacist to replace multiple doses of lower strength medications where clinically appropriate with a single dose of a higher-strength medication (only with the prescribing physician's approval). Prior to dispensing multiple doses of the lower strength medications, a written PA needs to be submitted for an internal review by Prime to determine medical necessity.

#### **Benefit Exclusions**

Benefit exclusions are services that are not covered under the Covered Person's benefit plan which include the following medications:

- Infertility medications
- Erectile dysfunction medications
- Cosmetic and hair growth medications
- Dietary supplements
- Drugs not approved by the FDA
- OTC drugs for CHIP/CHIP Perinate Covered Persons
- Contraceptive agents used for family planning for CHIP/ CHIP Perinate

### Where Prescription Drug Services are Filled

Prescription Drug Services can be filled at pharmacies participating in the Texas Medicaid Network. A listing of these pharmacies in the Texas Medicaid Network can be found in the **BCBSTX Provider Directory**. To verify pharmacy network participation or BCBSTX drug coverage, please contact Prime's Contact Center as follows:

- STAR Covered Persons at 855.457.0405
- CHIP Covered Persons at 855.457.0403
- STAR Kids (in the Travis service area) at 855.457.0757
- STAR Kids (in the MRSA Central service area) at **855.457.0758**

Retail pharmacies can dispense no more than a 34-days' supply, but most prescriptions can be written with refills.

#### **Prime's Information for Claims Processing**

BIN 011552 PCN TXCAID

The Group# is not required for STAR and CHIP claims processing.

### **Member Eligibility**

A Participating Pharmacy should verify the Covered Person's Medicaid coverage at the time of service.

A Participating Pharmacy can verify eligibility by calling the Texas Medicaid Healthcare Partnership (TMHP) at **800.925.9126** or go to TexMedConnect on the TMHP website and checking the Covered Person's Medicaid ID number (PCN).

Covered Persons may call BCBSTX customer service at **888.657.6061** with eligibility-related questions. If a Covered Person is unaware of which program he/she is enrolled in, the Covered Person may contact the Medicaid Managed Care enrollment broker. Covered Persons may call the Medicaid Client Line at **800.964.2777** for assistance with eligibility-related issues.

#### **Cost to Member**

Member Type	Copay for up to 34-day supply
STAR	No сорау
CHIP < 100% FPL	\$0 for generic/\$3 for brand
CHIP 101 – 150% FPL	\$0 for generic/\$5 for brand
CHIP 151 – 185% FPL	\$10 for generic/\$35 for brand
CHIP 186-200% FPL	\$10 for generic/\$35 for brand
CHIP Perinate	No сорау
CHIP AIAN	No сорау
CHIP No Cost Share	No сорау

#### **Advance Directives**

Participating Pharmacy must comply with the requirements of state and federal laws, rules and regulations relating to advance directives and in accordance with 42 C.F.R. §489, Subpart I.

#### **Child Protection**

Participating Pharmacy must testify in court as needed for child protection litigation if requested by Texas Health and Human Services Commission (HHSC).

### **Cancellation of Product Orders**

In the event a Participating Pharmacy in the Texas Medicaid program offers delivery services for covered product(s), such as durable medical equipment (DME), home health supplies, or outpatient drugs or biological products, and the Covered Person requests in written or oral representation to reduce, cancel, or stop delivery of the covered product(s), Participating Pharmacy must maintain records documenting the request.

### **Coordination of Benefits**

Participating Pharmacy must perform Coordination of Benefits in accordance with HHSC Uniform Managed Care Manual, Chapter 3.3 Section VI, C and HHSC Uniform Managed Care Pharmacy Claims Manual, Chapter 2.2 Section VI, A.

#### Tuberculosis (TB)

Covered Person(s) who may be or are at risk for exposure to TB must be screened for TB. An at-risk Covered Person(s) is a person who is susceptible to TB because of the association with certain risk factors, behaviors, drug resistance, or environmental conditions. The Participating Pharmacy must consult with the local TB control program to ensure that all services and treatments are in compliance with the guidelines recommended by the American Thoracic Society (ATS), the Centers for Disease Control and Prevention (CDC), and Texas Department of State Health Services' (DSHS) policies and standards.

#### **Non-covered Services**

If Participating Pharmacy receives a non-covered Prescription Drug Services for a Covered Person, Participating Pharmacy must inform the Covered Person of the cost and obtain a signed private pay form from the Covered Person prior to rendering the services. The private pay form may be found in the TMHP Provider Enrollment and Responsibilities.

#### **Delivery Service**

If Participating Pharmacy elects to provide delivery services to Covered Persons under the Texas Medicaid Network, Participating Pharmacy may not charge the Covered Person for a delivery fee. Pharmacy must adhere to the State's delivery incentive requirements found on the Pharmacy Provider Enrollment Application. If Pharmacy is in violation of this requirement, Prime, Benefit Sponsor or HHSC reserves the right to terminate Participating Pharmacy from the Texas Medicaid Network.

#### **Covered Person Protections**

If Participating Pharmacy is aware of any reports to authorities on abuse, neglect, or exploitation of a Covered Person, Participating Pharmacy must notify Prime of any such reports including but not limited to Participating Pharmacy self-reports and reports made by others.

### **Durable Medical Equipment**

If Participating Pharmacy processes or intends to process a durable medical equipment (DME) prescription, Prime encourages Participating Pharmacy to become Medicaidenrolled as a DME provider. Please refer to the State of Texas' Vendor Drug Program ("VDP") to request for a DME application. To be listed as a DME provider, a pharmacy must be a VDP pharmacy and attested with Texas Medicaid and Healthcare Partnership ("TMHP").

#### Important Toll-free Contact Numbers

Prime's Contact Center is available 24 hours/7 days a week:

- BCBSTX CHIP: 855.457.0403
- BCBSTX STAR: 855.457.0405
- BCBSTX STAR Kids (Travis service area): 855.457.0757
- BCBSTX STAR Kids (MRSA Central service area): 855.457.0758

Pharmacy prior authorization is available 24 hours/ 7 days a week:

- BCBSTX CHIP: 855.457.0403
- BCBSTX STAR: 855.457.0405
- BCBSTX STAR Kids (Travis service area): 855.457.0757
- BCBSTX STAR Kids (MRSA Central service area): 855.457.0758
- Pharmacy prior authorization fax: 877.243.6930

**Prime Therapeutics LLC** 

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